CE 0197

Syringe Pump

Sunfusion Series

Operator's Manual

Please read this manual carefully before use the device

Digitally signed by Potînga Stela
Date: 2023.06.28 13:57:26 EEST
Reason: MoldSign Signature
Location: Moldova

Contents

Warnings and Precautions

⚠Warnings:

- Before use, must check the pump, cables, and accessories to ensure that the pump works normally and safely.
- The user is obligated to perform calibration to ensure the accuracy of pump.
- Must connect the pump to grounded AC mains power source. Use the internal battery module to supply power instead of using the AC mains power without protective grounding in order to avoid hazards.
- Persons who do not receive training should not operate the pump.
- Operators must be appropriately trained to have a good command of necessary knowledge and operation competence on performing check, maintenance and repair.
- To avoid fire and explosion hazards, keep the pump away from the environment full with vibrations, dust, excessive temperature or humidity, as well as large electrical equipment etc.
- Do not operate the pump in the presence of flammable anaesthetics to prevent explosion.
- To avoid electric shock hazards, never open the enclosure or battery compartment for any reasons.
- The maintenance of device should be conducted by service personals who have received professional training.
- Always disconnect pump from mains power prior to maintenance and repair.
- Do not alter the devices without authorization of the manufacture (including software, hardware and construction).
- Need manually evacuate air bubbles in the syringe and extension tubing before starting the pump.
- Control the height between pump and patient's heart within ±100 cm. The shorter the height is, the more precise the pressure detector can be.
- Should timely replace the deformed or broken plunger release levers in order to avoid siphoning hazards which cause free flow of residual liquids to patient.
- Ensure that the syringe barrel is securely inserted into the flange clip. Otherwise, hazards of no flow or over flow of drug may be intrigued due to siphoning, which may do harm to the patients.
- Carefully put the cables of supply and accessories to avoid patient strangulation or entanglement, cables entanglement, and electrical interference.
- Setting the alarm parameters like voice and threshold corresponds to actual situations. It may cause hazards if the alarm voice is too low to be noticed by operators.
- Never only rely on the auditory alarm system. More attentions should be paid on actual clinical situations of patients and pump's working status.
- To warrant accuracy and essential performances of the pump, use the syringes specified in this manual (see details in chapter 17); The accuracy cannot be guaranteed if an unlisted syringe is used without calibrating according to the instructions for use.

- The change of infusion speed and the increase of air infusion risk may be generated by connection of patient line and other improper administration sets or accessories (especially for the equipment with gravity syringe devices).
- The accuracy of devices cannot be ensured in the cases that working cycle is too short, the inject needle is too small, the protective measures are insufficient under worst conditions, and the administration sets is blocked, etc.
- The pump may be interfered by a large electromagnetic field, abnormal current and electrostatic discharge (ESD) which exceed the EN/IEC60601-2-24 and EN/IEC60601-1-2 Provision. Please consult the authorized manufacturer if the pump is expected to be used under special conditions.
- The battery of devices only can be supplied by our company. If replacement is needed, please contact service personals to help you install properly in order to avoid undesirable risks caused by incorrect replacement.
- Please implement inspection of charge-discharge before using to avoid working halt because of the accident interruption of power. If the battery cannot be charged or discharged, please contact an authorized distributor or manufacturer for help.
- When the fuse is damaged or broken, please contact the qualified service staffs to replace it with suitable fuse.
- Once fault appears, immediately remove the pump from service and consult manufacturer or authorized distributors to perform maintenance.
- Never use other improper infusion controllers on devices to avoid safety hazards.
- Never touch the patient while connecting to external devices through signal I/O port, to avoid exceeding standard patient current leakage.
- When the device is used together with electrosurgical equipment, patients' safety should be ensured.
- Environmental protection: When pump and accessories (batteries, syringes, etc.) are about to exceed their service life, please properly deal with them according to relevant environmental protection law.
- The package materials must be disposed in accordance with local regulations or the hospital's waste disposal system.
- Place the package materials at a place out of children's reach.

Precautions:

- Please read the operator's manual carefully before using the devices.
- After proper installation, start the device by correctly setting each parameter in accordance with clinical treatment requirements.
- Firmly and properly install the devices to avoid falling or sliding hazards caused by pulling pipelines by accident.
- Do not put devices at the edge of bed without fence.
- Notify the manufacture to change the sunken operation buttons due to long time using to avoid false triggering.
- Keep the device dry. If cleanness is needed, please use wet rag and proper detergent but never use organic solvent, such as benzene and butanone etc.
- Conduct inspection of battery charge-discharge status at least once every 3 months

to prevent hazards or damages caused by low-power. Timely charge the battery with grounded AC power when there is alarming of low-power.

- Battery maintenance and replacement should be conducted by qualified service personals.
- Inspect the whole device at least once half year.
- The tension on the extension tubing should not exceed 5N. Otherwise, it may cause danger.
- Set the volume to be infused (VTBI) as similar to the actual capacity of syringe as possible.
- Do not expose the device into a direct sunlight, excessive temperature or humidity.
- Please install the devices in a place where easy to observe, operate and maintain the devices.
- Please never connect the devices not specified by company to the multi-function interface.
- Directly unplug the power cable from three-pin socket to disconnect the power supply of device.
- Install the device at a place where the power cable can be easily plugged out from the three-pin sockets.
- In the process of infusion, over-infusion, under-infusion and backdraft are effectively prevented by devices that are designed to precisely control infusion speed and monitors the speed and direction of the stepping motor in real time.
- No direct contact between the drugs/patients and the devices, so that biocompatibility test is not required.
- Contact us for more necessary information and technical supports specified in the EN/IEC60601-1.

Symbols

Not all symbols are useful.

AC Power	Type CF equipment (protection from electric shock)	START
DC Power	Caution!	STOP/BACK
SILENCE	ON/OFF	BOLUS
Battery	IP24 Waterproof and dust proof level	Syringe
Multi-function interface	Equipotential	CE 0197 CE mark
SN Serial number	Please read operator's manual before using	EC REP Authorized representative in the European community
Manufacturer	Date of manufacture	Collect Separately

1 Overview

1.1 Introduction

1.1.1 Working Principle and Intended Use

Used together with the matching disposable syringe, the Sunfusion serial Syringe pumps (hereinafter referred to as syringe pump) implement its infusion function through a microprocessor which accurately controls the stepper motor to produce the translational thrust through the mechanical transmission devices to push the syringe plunger down into barrel. Equipped with various sensors, Sunfusion syringe pump is able to precisely control the infusion processes, like infusion rate, volume etc, as well as able to monitor the infusion process in real time. That makes Sunfusion pump a high precise intelligent syringe pump.

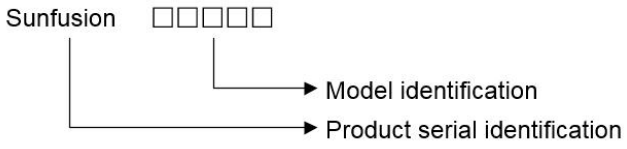
Not only can the syringe pump be compatible with 3 kinds of syringes specified in this manual (refer to Chapter 17), but compatible with any syringe brands after correct calibration. Various alarm functions are supplied with devices, prompt information is synchronously displayed with a TFT colorful touch screen, and safe and convenient operation is ensured by reasonable interface design.

Syringe pumps are intended for clinical treatments that require precise control of infusion rate (or volume) and monitoring of the infusion process, such as clinics, ICUs, operation rooms, emergency rooms, and general wards.

1.1.2 Contraindications

Nothing.

1.1.3 Model Coding



Different models are distinguished by different optional configurations.

1.1.4 Specifications

Applicable syringe size	2ml/3ml, 5ml, 10ml, 20ml, 30ml, 50/60ml
Flow Rate	2ml/3ml:0.01~60ml, 5ml:0.01~150ml, 10ml:0.01~300ml, 20ml:0.01~600ml, 30ml:0.01~900ml, 50/60ml:0.01~2200ml
Rate Step	0.01ml/h
BOLUS Rate & VTBI (Volume to be infused)	2ml/3ml:0.01~ 60ml/h 0.1~2ml 5ml:0.01~ 150ml/h 0.1~5ml 10ml:0.01~300ml/h 0.1~10ml

	20ml:0.01~ 600ml/h 0.1~20ml 30ml:0.01~ 900ml/h 0.1~30ml 50/60ml:0.01~2200ml/h 0.1~50ml
BOLUS Rate step	0.01ml/h
FF (Fast Forward)	2ml/3ml:0.01~60ml, 5ml:0.01~150ml, 10ml:0.01~300ml, 20ml:0.01~600ml, 30ml:0.01~900ml, 50/60ml:0.01~2200ml
FF volume range	0 ~maximal volume of syringe
Manual KVO Rate	0.01～5.0ml/h (0.01ml step)
Manual KVO Volume	2ml/3ml:0.01~0.2ml (0.01ml step), 5ml: 0.01~0.2ml (0.01ml step), 10ml: 0.01~0.2ml (0.01ml step), 20ml: 0.01~0.5ml (0.01ml step), 30ml: 0.01~0.5ml (0.01ml step), 50/60ml: 0.01~1ml (0.01ml step)
VTBI (volume to be infused)	0.01～9999.99ml, (0.01ml step)
Cumulative infusion volume	0.01～9999.99ml, (0.01ml step)
Rate accuracy	Within ±2% (after calibration)
Pressure units	MPa, kPa, mmHg, inH_2O, psi ,mbar
Occlusion pressure	Level 1-13 (10、20、30、40、50、60、70、80、90、100、110、120、130)kPa
Alarms	Infusion finished, near infusion end, VTBI completed, near VTBI end, extension tubing off(optional), pre-occlusion alarm(optional), KVO completed, standby task completed, infusion is blocked, syringe falls off, syringe is improperly installed, forgotten operation, low battery, battery empty, abnormal running state, equipment failure, power failure, battery disconnected etc.
Prompts	Parameter overrun, infusion begins, AC power has been pulled out, speed overrun, Uncalibrated accuracy.
Maximum infusion volume under single fault condition	1mL
Power source	100~240VAC, 50/60Hz; Internal rechargeable 11.1V Li battery with capacity≥2600mAh, 8 hours backup time at the rate of 5ml/h for a fully charged battery; External DC power supply, input voltage 15V, input current 1.2-1A.（The DC power supply shall meet the requirements of EN/IEC 60601-1）
Power Consumption	25VA
Fuse Specification	T2A/250VAC
Equipment classification	Class I, Type CF, Continuous operation
IP classification	IP24
Working conditions	Temperature:+5℃~+40℃, Relative humidity:20~90%, Atmospheric pressure:86.0kPa~106.0kPa
Transport & Storage conditions	Temperature:-20℃~+55℃, Relative humidity:≤93%, Atmospheric pressure:50.0kPa~106.0kPa
Dimensions	301mm（L）×183mm（W）×82mm（H）

Net weight	About 2.0 kgs
Gross weight	About 3.4 kgs
Safety standards	EN/IEC 60601-1 Medical electrical equipment -- Part1: General requirements for basic safety and essential performance EN/IEC 60601-2-24 Medical electrical equipment -- Part2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers EN/IEC 60601-1-8 Medical electrical equipment -- Part1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EMC standard	EN/IEC 60601-1-2 Medical electrical equipment--Part1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
Recommended syringe	Reference to Chapter 17. Any syringes can be used after correct calibration.
Applied part	Syringe extension tube

Attention:

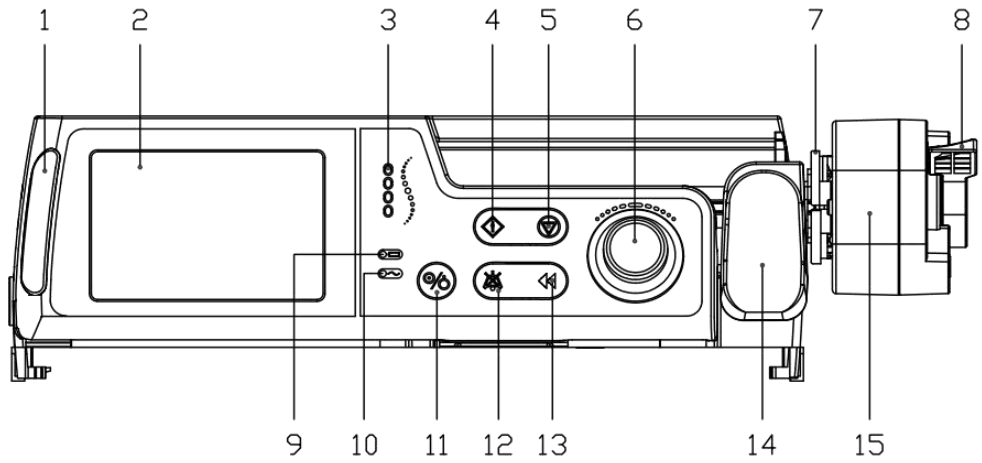
- Syringe and extension tubing applied shall be sterilized with ethylene oxide and comply with the standards of ISO7886-1 Sterile Hypodermic Syringes for Single Use. The syringes or extension tubes which do not comply with this standard may lead to incorrect infusion rate, drug residues and other possible hazards.
- The accuracy of the infusion rate is affected by various factors such as the syringe brand, the ambient temperature, and the concentration of the liquid.
- Please regularly check and calibrate the accuracy of devices.

1.1.5 **Service Life**

Seven years.

1.2 **Appearance**

1.2.1 **Front View**



1. **Alarm indicators**

   The alarm indicator indicates the alarm priority with different background colors and flicker frequency.

2. **Display touch screen**

   Synchronously display relevant parameters: infusion mode, infusion rate, cumulative infusion volume, VTBI (Volume to be infused), drugs, dynamic pressure, syringe size, time, syringe brand, etc.

3. **Working indicators**

   The working indicator illuminates in sequence up to down while the pump is working; and it darkens while the pump stops working. The faster the infusion rate is, the shorter the cycle time will be.

4. **START button**

   After correct installation and setting of relevant parameters, press the "START" button to start infusion.

5. **STOP/BACK button**

   - When in running state, press the “STOP/BACK” button to stop infusion.
   - When in alarming state, press the “STOP/BACK” button to terminate the alarm (except for equipment failure, system power down, and battery runs out).
   - On any sub-interface, press the “STOP/BACK” button to return to the main interface or to the previous interface.

6. **Rotary Knob**

   - Rotate the knob left to move “cursor” up or left, rotate the knob right to move the “cursor” down or right.
   - When editing parameters, rotate the knob left or right to change the value of parameters.
   - Press Knob for “select” or “confirm” function.
   - When in the parameter setting interface, move the “cursor” to intended position and then press Knob to edit relevant parameters. While editing parameters, the cursor is locked and cannot be moved; press Knob again to unlock the cursor.

7. **Syringe Plunger Holders**

   Hold the syringe plunger securely in place.

8. **Syringe Plunger Release Levers**

   Squeeze it to open and close the syringe plunger holders and to move the pushing block forward or backward.

9. **Battery Indicator (Blue)**

   - On: It is on while the pump is supplied by internal battery.
   - Off: It is off while the pump is shutdown or supplied by AC power; or no battery.

10. **AC Mains Power Indicator (Green)**

    - On: It is on while the pump is connected to AC mains power.
    - Off: It is off while the pump is not connected to AC mains power.

11. **ON/OFF Button**

    - Under shutdown state, press and hold “ON/OFF” button to switch pump on.
    - Under standby state, press and hold “ON/OFF” button for 3 seconds to switch

pump off; shortly press to set standby time.

- If the screen is locked while the pump is running, shortly press “ON/OFF” button for 1 second to unlock the screen.

12. SILENCE Button

- When high priority alarm occurs, press “SILENCE” button to pause the alarm sound for 1 minute. 1 minute later, silence state is automatically cancelled and the loudspeaker restores the previous alarm state.
- When low priority alarm occurs, press “SILENCE” button to pause the alarm sound for 1 minute; meanwhile, the buzzer sounds “Di” every 2s. 1 minute later, silence state is automatically cancelled and the loudspeaker restores the previous alarm state.
- Under running state, press and hold SILENCE button for 2 seconds to lock screen.

13. BOLUS Button

- FF (Fast Forward):

  When the pump is at non-operation state, single-click “BOLUS” button once to enter the FF setting interface to set FF rate. After parameters adjustment, follow the instructions to press and hold on the “BOLUS” button to run the pump according to the FF parameters.
- BOLUS: when the pump is running, single click BOLUS button to enter BOLUS setting interfaces to set BOLUS rate and VTBI.
  1) Shortly press BOLUS button once to enter AUTO-BOLUS mode: Pump will run at predefined AUTO-BOLUS parameters; and then return to normal infusion until the predefined BOLUSE VOLUME is completed. Press STOP/BACK button to terminate AUTO-BOLUS mode and the pump will stop working.
  2) Press and hold BOLUS button to enter MANUAL-BOLUS mode. Pump will run at manual setting parameters; and then return to normal infusion until the button is released or VTBI is completed.
- FF mode restrains Air-in-line alarm condition only. BOLUS mode does not restrain any alarm conditions.

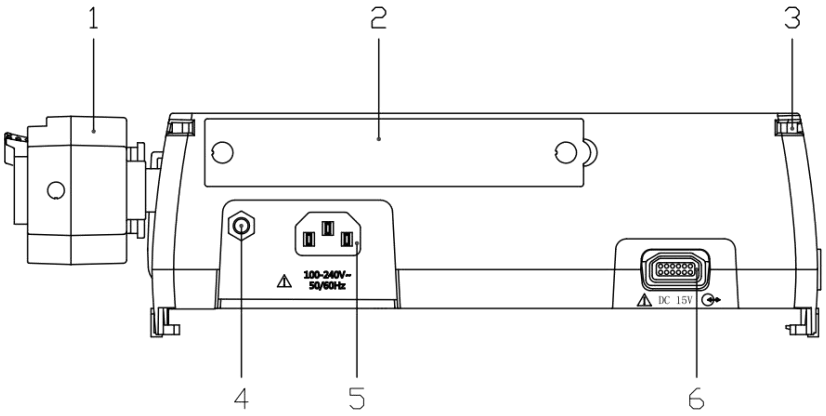
14. Syringe Barrel Clamp

The clamp holds the syringe barrel securely in place.

15. Pushing Block

The pushing block drives the syringe plunger forward at a controlled and precise rate to implement infusion function.

1.2.2 **Back View**



1. Pushing block

2. Battery Compartment cover

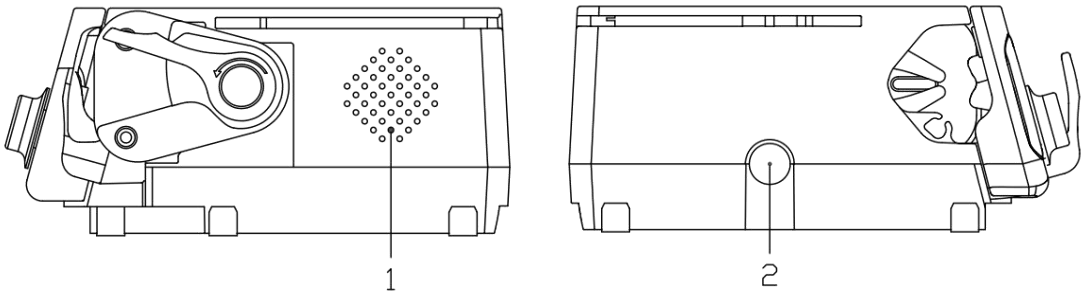
3. Slide guide: For combining multiple pumps

4. **Equipotential terminal:** When the pump is used together with other equipment, the equipotential ends of the pump and the other equipment should be connected with equipotential wires to eliminate the ground potential difference between different devices, which ensures devices work safely and normally.

5. AC Power Connection Port: connect to mains power source with power cable;

6. Multi-function Port: DC power input Port & RS232 Port (This connection Port is mainly used for connection with workstations; Do not connect other devices into this port.)

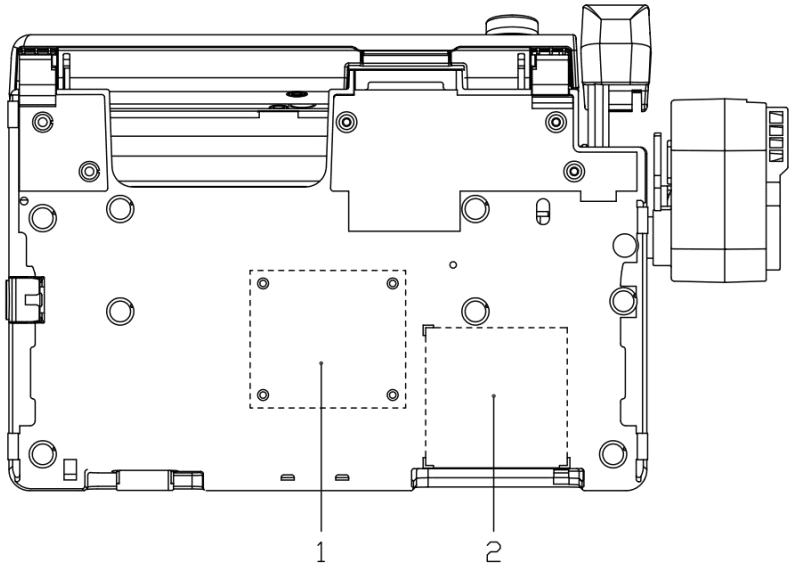
1.2.3 **Side View**



1. **Loudspeaker Holes**

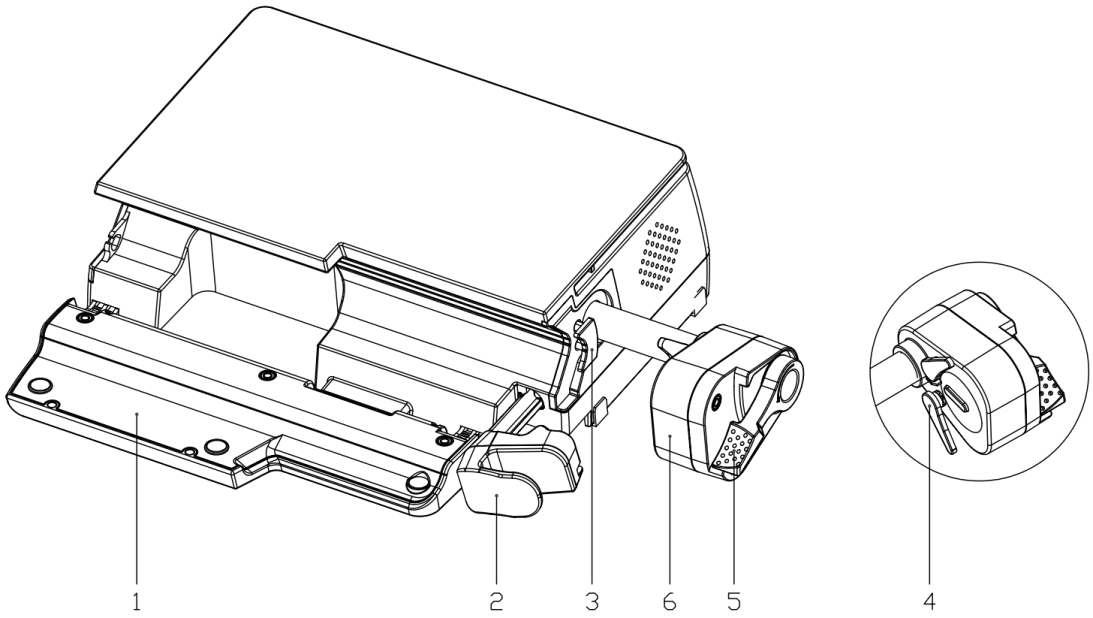
2. **Lock Catch** Used for reinforcement of multiple pumps and unlock.

1.2.4 **Bottom View**



1. Mounting Holes of Pole Clamp
2. Nameplate

1.2.5 **Detail Diagram with Door Open**



1	Door	5	Syringe Plunger Release Levers
2	Syringe Barrel Clamp	6	Pushing block
3	Flange Clip	7	Loudspeaker Holes
4	Syringe Plunger Holders		

1.2.6 User Interface

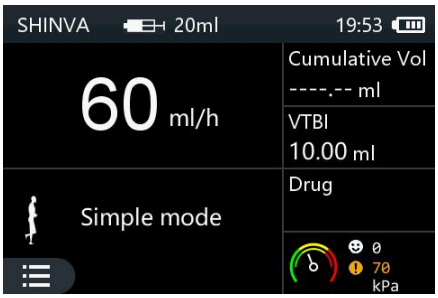


Figure 1-1 Main interface

1. **Status bar**
   - Display: syringe brand and size, time, battery status, wireless connection status, screen lock status, cascade statue, etc;
   - Display Alarm information, like battery empty, forgeting operation, ect.
2. **Information bar**

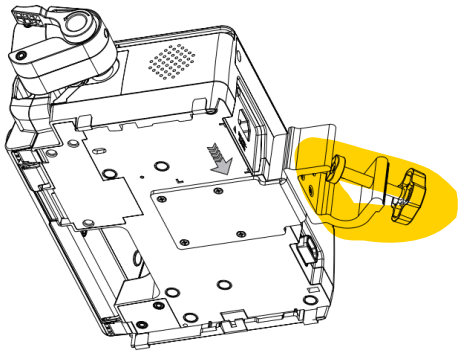
   Display parameters' values of current infusion mode, including rate, cumulative volume, VTBI, remaining time, etc.
3. **Prompt bar**
   - Display the current infusion mode and drug name.
   - Dynamically display pressure values
     1) The pointer points to the green area, indicating that the current pressure is less than 30% of the occlusion pressure;
     2) The pointer points to the yellow area, indicating that the current pressure is more than 30% and less than 60% of the occlusion pressure.
     3) The pointer points to the red area, indicating that the current pressure is more than 60% and less than 100% of the occlusion pressure.
   - The icon "" indicates the running state and the running speed. The icon "" is still while the pump is at non-operation state. The icon "" is running dynamically while the pump is on operation.
   - Menu option icon "": press it to enter the menu interface to set relevant parameters.

1.2.7 Cursor

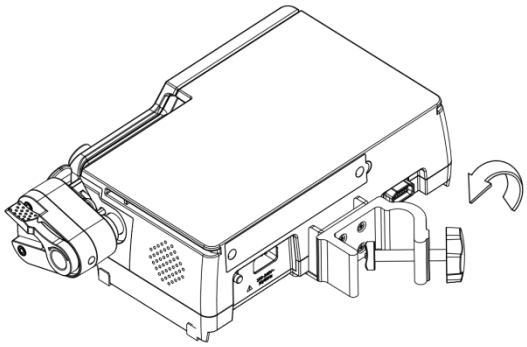
- In main interface, menu interface, and parameter setting interface, move the Cursor by switching the Rotary Knob left or right (refer to 1.2.1 Rotary Knob);
- While the Cursor is moved to a certain parameter or selection, the background color of relevant place will change from back to blue (different pump models have different background colors);
- While the Cursor is moved to an intended place, press the Rotary Knob to confirm and move to next step.

2 Installation

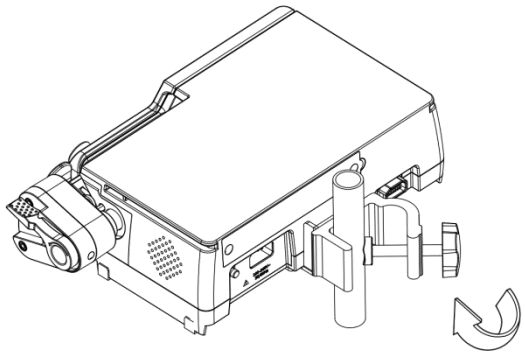
2.1 Install Pump



1. Align the holes of the Pole Clamp with the screw holes on the bottom of the pump and tighten the screws.



2. Unscrew the clamp knob until it fits to the pole by rotating anticlockwise.



3. Clockwise screw clamp knob and ensure that the pump is securely fastened to the pole.

⚠Caution:

- Ensure pump is securely fixed;
- Changes of mounting position and severe vibration may affect the accuracy of device.

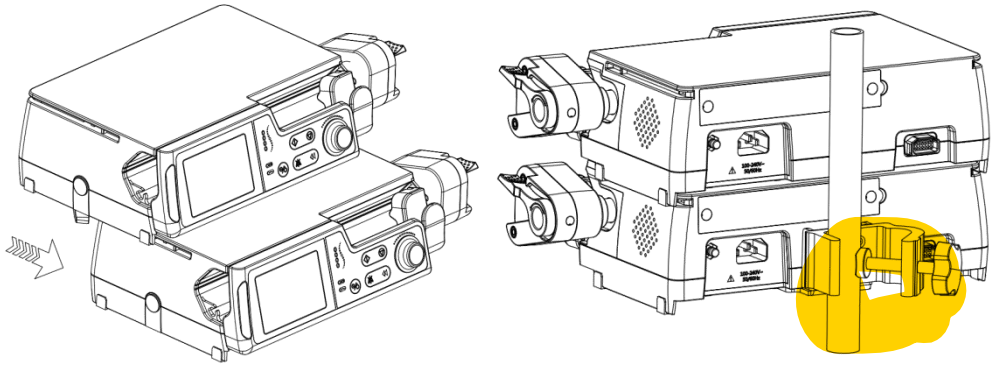
Attention:

- Before installing, carefully check the stability of the support system.

2.2 Combination of Multi-Pumps

The pump can be stacked up to two (Infusion pump and syringe pump can be cross-assembled). Align the slide guide on the bottom of the upper pump with the guide slot on the top of the lower pump, and then push it slowly until two pumps are securely locked. If detaching two pumps, press the lock catch on the upper pump to pull the upper

pump out of the lower.

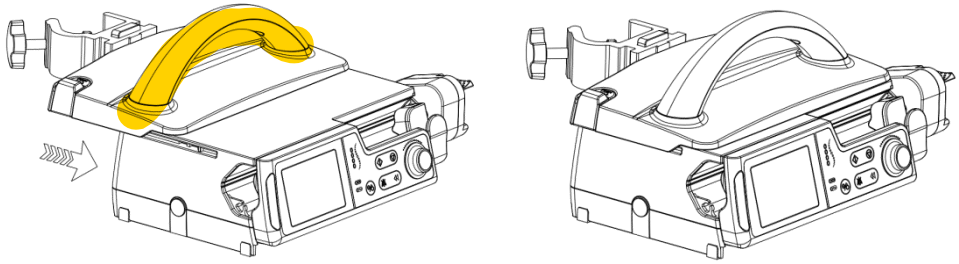


Attention:

- The pump must be placed in a horizontal position.

2.3 Install Simple Handle

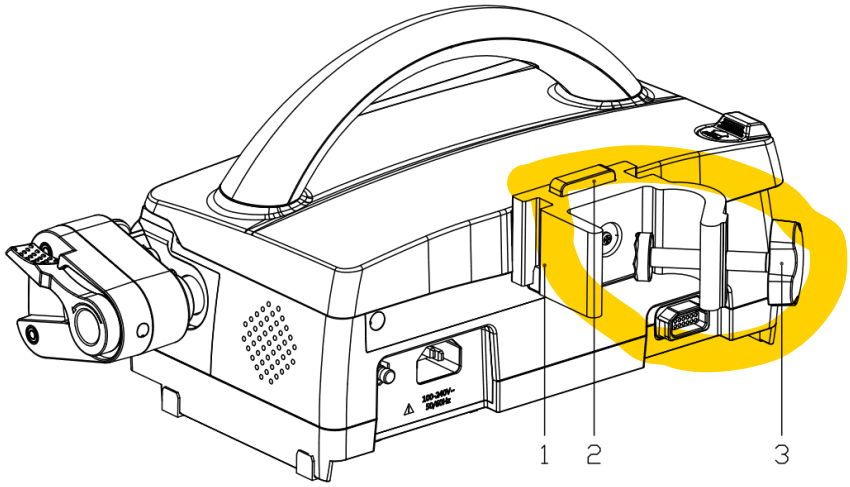
Align the slide guide of the simple handle with the guide slots on the top of the lower pump, then slide forward until the simple handle and pump are locked. Press the lock catch on the simple handle to separate it from the pump.



Press the button on Pole Clamp to adjust its horizontal or vertical position. Screw the clamp knob to fix the pump to the horizontal or vertical pole.

Square pole: width 15mm, length 15-32mm

Circular pole: outer diameter Φ15-32mm



1—Pole Clamp 2—Button 3—Clamp Knob

Attention:

- When using a simple handle to makes pump as a portable device, only up to two pumps are allowed, otherwise there is a risk of damage to the handle.

2.4 Connect to AC Mains Power

The three-pin socket must be protectively grounded with grounding wire. If grounding of AC mains power is doubt, please use the internal battery module to supply power and contact the hospital's electrical technician or our company.

⚠Caution:

- Never touch the power plug with wet hands! If there are drug liquid or other residues in the power socket, plug or the surrounding area, measures should be taken to thoroughly clean and dry the pump before connecting to mains power. Otherwise, it may cause undesirable safety accidents.

Attention:

- AC power supply voltage range: ~100-240V, 50/60Hz.
- AC power cable should be inserted securely
- Pulling out the plug is a necessary measure for separating the pump from the mains power. To make it easy to connect and unplug the power cable, sufficient spaces around the pump should be provided.

3 Parameter Setting

3.1 Description of Each Option

1. The parameter setting can be completed by the touch screen or by the Rotary Knob. For more operation instructions of the Rotary Knob, please refer to 1.2.1 front view.
2. "  " option means function of "confirm" or "save".
   In the parameter setting interface, selecting the "  " option will save the current parameters and directly return to the previous interface.
   If a certain function has two or more parameters to be set in succession, after setting the first parameter, select the "  " option to jump to the setting interface of next parameter.
3. "  " option indicates to cancel the current setting or withdrawing the edition, and the interface directly returns to the previous one.
4. "  " and "  " option indicates to increase or decrease the value of the parameters.
5. "  " round slider, move it to the left to decrease the parameter value or level, and move it to the right to increase the parameter value or level.
6. "  " and "  " options are "Page Forward" and "Page Back".
7.  Home option is on every page, press it to return to main interface directly.
8. Once buttons, Rotary Knob or touch screen are operated, buzzer will sound a beep.

Attention:

- "  ", "  ", "  ", "  ". When the background color of these four options is bright, it is available to fulfill their corresponding functions. When their background colors are

gray, it is unavailable.

3.2 Syringe Brand

1. On the main interface, select menu option "☰" → enter menu interface as shown in Figure 3-1 → select "Brand" option to choose the syringe brand according to actual needs.

Figure 3-1

2. When other syringes not included in the brand library are intended to be used with pump, must perform correct calibration before using. Refer to 8.3 for details.

3.3 BOLUS

1. Select menu option "☰" → select "BOLUS" option to enter the BOLUS setting interface as shown in Figure 3-2.

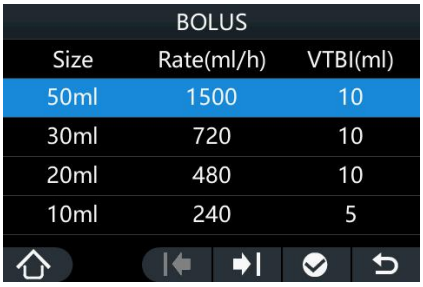


Figure 3-2

2. Select a syringe size to enter the parameter setting interface of rate or VTBI (volume to be infused).
3. Move the Cursor to an intended position to choose and adjust the parameter values. User can also follow the instructions in section 1.2.1 to set relevant parameters.
4. The BOLUS volume is accumulated at the beginning of the BOLUS mode, and buzzer will sound "Di" every 0.5ml volume.
5. BOLUS volume is counted to the Cumulative infusion volume.

3.4 FF (Fast Forward)

1. Select menu option "☰" →select "FF" option to enter the FF setting interface as shown in Figure 3-3.

5.5

Figure 3-3

2. Select the syringe size, and enter the parameter setting interface of rate or VTBI (volume to be infused).
3. Move the Cursor to an intended position to choose and adjust the parameter values. When VTBI is set as 0, the VTBI displayed is "∞" which means that drug volume can be infused infinitely.
4. User can also follow the instructions in Section1.2.1 to set relevant parameters.
5. Under non-operation state, double click and hold on BOLUS button to keep machine working without stop.

3.5 KVO

1. Select menu option "  "→select "KVO" option to enter the KVO setting interface;
2. There are "AUTO KVO" and "MANUAL KVO" and "KVO OFF" three selections. The default option is AUTO KVO.
3. If AUTO KVO is selected, the relevant parameters (Rate, VTBI) are unable to change:
   - While infusion rate ≥10.0ml/h, KVO rate is 3.0 ml/h;
   - While 10.0ml/h> infusion rate≥1.0ml/h, KVO rate is 1.0ml/h;
   - While infusion rate <1.0ml/h, KVO rate is equal to current infusion rate;
   - KVO VTBI is fixed at 0.5ml. and alarm of KVO completed will be trigged if the VTBI is completed.
4. Under MANUAL KVO mode, KVO rate and VTBI are settable and the setting interface is shown as figure 3-4:

Figure 3-4

   - Select the syringe size, and enter the parameter setting interface of rate or VTBI.
   - Move the Cursor to an intended position to adjust the parameter values.
5. If MANUAL KVO mode is selected and relevant parameters are set, the pump will automatically enter the KVO mode and runs at the preset MANUAL KVO rate after the infusion presses is finished. The pump stops running until the KVO VTBI is completed or "STOP" button is pressed, whist an alarm of "KVO completed" is generated.

Attention:

- While setting parameters of BOLUS, FF and Manual KVO, rate is first, and then VTBI. After rate is set, select "✓" option to save current parameters and automatically move to the VTBI setting interface. If select "↩" option, the parameters will not be saved and return to the previous interface.
- After both rate and VTBI parameters have been set, the system turns back to the interface as shown in Figure 3-2, Figure 3-3 and Figure 3-4, select "✓" option again to save these parameters.
- The range and stepping of BOLUS, FF and Manual KVO refer to 1.1.4.
- The FF and BOLUS parameters in the menu interface is in consistent with the shortcut interface introduced in Section 1.2.1.

3.6 Occlusion Pressure

Select menu option "☰" → select "OCCL" option to enter the occlusion pressure setting interface as shown in Figure 3-5.

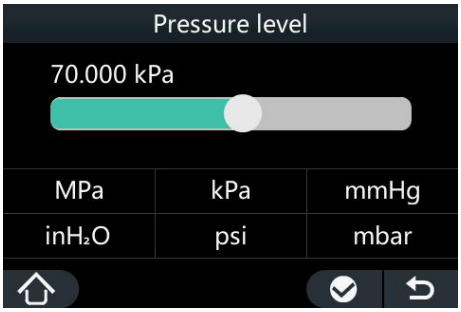


Figure 3-5

3.6.1 Select Occlusion Pressure Level and Unit

1. Press and hold the round slider "◯" to move left or right; or switch the Rotary Knob to adjust the occlusion pressure level.
2. 13 occlusion pressure levels are available (refer to 1.1.4). Corresponding pressure value will be displayed on the LCD as the level of occlusion pressure changes. The default occlusion pressure level is 70kPa. (Note: User is obligated to choose the occlusion pressure value according to actual needs.)
3. 6 pressure units are available (refer to 1.1.4). Original pressure values will automatically convert into the values of current unit as the pressure unit changes. The default occlusion pressure unit is kPa. (Note: User is obligated to choose the occlusion pressure value according to actual needs.)
4. Select "✓" option to complete pressure level setting; select "↩" option to return to the previous interface and current parameters are not saved.

Attention:

- Discomfort may be generated by choice of a high occlusion pressure level;
- Pay more attention on patient's physical condition after setting an occlusion pressure;

- Urgent measures should be taken immediately if abnormal situations occur.

3.6.2 Dynamic Pressure Monitoring

1. During infusion process, dynamic pressure values will be displayed on the prompt bar of the main interface (right corner of the main interface) in real time. That makes it convenient to find blockage in administration set and timey take measures to avoid hazards. For details, please refer to 1.2.6 display: Prompt Bar.
2. The permissible occlusion pressure value error: ± 10kPa for all levels.

3.7 System Setting

Select “ ” option → select “System settings” option to enter the system settings interface as shown in Figure 3- 6.

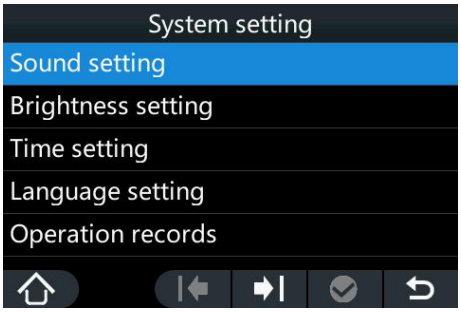


Figure 3- 6

3.7.1 Sound Setting (Human Voice)

1. Select “menu” “ ”option → select “System setting” option→ “Sound setting” option to enter the setting interface.
2. Press and hold the round slider “ ” to move left or right or switch the Rotary Knob to left or right to adjust the Sound level.
3. Select Sound level: off, on (7 levels are available). Level 7 is the maximum volume. The default level is level 4.
4. Only the sound level of voice broadcasting is changeable, alarming sound is fixed.
5. Select “ ” option to complete the Sound setting; select “ ” option to return to the previous interface and current parameters are not saved.

3.7.2 Brightness Setting

1. Select menu “ ” option →select “System setting” option→ “Brightness setting” option to enter the setting interface.
2. Press and hold the round slider “ ” to move left or right; or switch the Rotary Knob to left or right to adjust the brightness.
3. Choose the brightness level: 10-100. Level 100 is the maximum brightness. The default level is level 100.
4. Select “ ” option to complete the brightness setting; select “ ” option to return to

the previous interface and the current parameters are not saved.

⚠Caution:

- When the pump is powered by internal battery, slight brightness can save battery power.

3.7.3 Time Setting

1. Select menu "  " option →select "System setting" option→ "Time setting" option to enter the setting interface.
2. Rotate the Rotary Knob to move "Cursor" to time and date option to enter the setting interface: the date is first, and then time;
3. After correctly set the date, select the "  " option to save and automatically move to time setting interface; select "  " option to return to the previous interface and current parameters are not saved.
4. 2 date formats are available: "yyyy-mm-dd" and "dd-mm-yyyy". The date format of history records will automatically update as the date format changes.

3.7.4 Language Setting

1. Select menu "  " option →select "System setting" option→ "Language setting" option to enter the setting interface.
2. Select one language, a prompt "Change to a new system language and a default brand？" will be displayed on the interface.
3. Select "  " option to complete the setting; select "  " option to return to the previous interface and current parameters are not saved.
4. After system language is selected and loaded, system will lead you to choose a new default brand. After new brand is set, the system automatically returns to the system setting interface.

3.7.5 Operation Records

1. Select menu "  " option →select "System setting" option→ "Operation records" option to enter the setting interface.
2. Select "  " and "" option to check history records, the system can save up to 20000 records.
3. The records are divided into three types:
   - Alarm: record the name and time of the alarm event（specific alarm priorities and alarm conditions, please refer to chapter 6）;
   - Finish: save parameters including infusion start and end time, work mode, running speed, infusion volume, drug;
   - Modify: record the content, date and time of modification;
4. After the history records are full, the premier records will be overwritten by the latest history in order.

5. After shutdown, the electronic records retention time is 20 years.
6. The history records can still be saved after the power supply and the battery are cut off at the same time.

3.7.6 Treatment Records

1. Select menu “ ” option →select “Setting” option →“ ”→ “Treatment records” to enter the interface.
2. At least 50 pieces history therapy records can be stored. And any of history therapy method can be selected to as the current therapy method.

3.7.7 Lock Screen Time Setting

1. Select menu “ ” option →select “System setting” option →“ ” →“Lock screen time setting” option to enter the setting interface.
2. Press and hold the round slider “ ” to move left or right; or switch the Rotary Knob to left or right to adjust lock time.
3. Select one time: off, 5seconds, 10seconds, 30seconds and 1-10min are available. The default lock time is “off”, which means that the lock screen will not be enabled.
4. Select “ ” option to complete the setting; select “ ” option to return to the previous interface and current parameters are not saved.
5. If there is no operation or no alarm occurring during the period of auto-lock time, the buttons and screen of the pump will be automatically locked, and an “ ” icon appears in the status bar. If press any button (except "ON/OFF"), a prompt " Press the ‘on/off’ for 1sec to unlock” will appear on the screen.
6. Follow the prompt “ Press the ‘on/off’ for 1sec to unlock” to unlock screen; if successfully unlock, the buzzer will sound a beep and “ ” icon disappears.

3.7.8 Forgotten Operation Reminder Setting

1. Select menu “ ” option →select “System setting” option →“ ”→ “Forgotten operation reminder setting” to enter the setting interface.
2. Press and hold the round slider “ ” to move left or right or switch the Rotary Knob to left or right to adjust time.
3. Select one time: 1-10min. The default time is 10min.
4. Select “ ” option to complete the setting; select “ ” option to return to the previous interface and current parameters are not saved.
5. If the non-operation duration is equal to the preset forgotten operation duration, sound and light alarming signals will be triggered to remind user of operation. Cancel the alarm by any operation action.

3.7.9 Soon Finish Alarm Time Setting

1. Select menu “ ” option → select “System setting” option → “ ” → “Soon finish alarm time setting” to enter the setting interface.
2. Press and hold the round slider “ ” to move left or right or switch the Rotary Knob to left or right adjust time.
3. Select one time: 1-30min. The default time is 2min.
4. Select “ ” option to complete the setting; select “ ” option to return to the previous interface and current parameters are not saved.
5. When the infusion time calculated according to the remaining volume and rate is equal to the set soon finish alarm time, near finish alarm will be given.

3.7.10 Night Mode Setting

1. Select menu “ ” option → select “System setting” option → “ ” → “Night mode setting” to enter the setting interface.
2. Night mode is default as off. Touch the “Night mode” option or press the Rotary Knob to enable the night mode.
3. Set the parameters such as “Start time”, “Stop time”, “Sound” and “Brightness” as reference in 3.7.1-3.7.3.
4. Select “ ” option to complete the setting; select “ ” option to return to the previous interface and current parameters are not saved.
5. If night mode is on, system will start the night mode according to the setting time. At the start time, the volume and brightness will change according to the night mode. When reaching the night mode stop time, the volume and brightness will restore the original set values of non-night mode.

Attention:

- Before enabling the night mode, please check the set voice volume and brightness carefully. If the set value is too low, potential risks may occur.
- While night mode, sound and brightness cannot be adjusted. If there is any attempt to change, a prompt “Setting invalid while night mode” will be given.

3.7.11 Patient Information

1. Select menu “ ” option → select “System setting” option → “ ” → “Patient information” to enter the interface.
2. User can edit department code and Bed No.. After the pump is connected with infusion management system, the patient information, including MRN, name, department, gender, and so forth, can be delivered by central station.
3. Select “ ” option to complete the setting; select “ ” option to return to the previous interface and current parameters are not saved.

3.7.12 Version Information

1. Select menu “ ” option →select “System setting” option → “ ” →“Version” to enter the interface.
2. Software version, built time and a QR code (scan it for more version information) will be displayed on the interface.

3.7.13 System Maintenance

1. Select menu “ ” option →select “System setting” option → “ ” → “System maintenance” to enter the interface.
2. Enter the password to perform system maintenance, including pressure calibration, accuracy calibration, and recovery, etc.
3. Consult the manufacturer for system maintenance password.

3.7.14 Max-Limit Function

1. Select menu “ ” option →select “System setting” option → “ ”→ “Max-Limit” to enter the interface.
2. The Max-Limit is disenabled by default. Click the ON/OFF area or press rotary knob to enable Max-Limit function;
3. If Max-limit is enabled, the limit range of Max-rate and Max-VTBI can be set:
   - Settable Max-rate range is 0.10mhl/h～2200ml/h and;
   - Settable Max-VTBI is 0.10ml～9999.99ml;
   - If the Max permissible rate of syringe is less than 2200ml/h (like 5ml syringe), then the settable limit range is in consistent with the specification in Section 1.1.4.
4. If Max-limit is disenabled, the settable ranges of rate and VTBI are consistent with the ranges specified in 1.1.4 section.

3.7.15 Delay Start Function

1. Select menu “ ” option →select “System setting” option → “ ”→ “Delay Start” to enter the setting interface.
2. The delay start is disenabled by default. Click the function area or press rotary knob to enable DELAY START.

3.7.16 Drug Priority

1. Select menu “ ” option →select “System setting” option → “ ”→ “Drug priority” to enter the setting interface.
2. User can select a drug in list to set its priority according to daily need. Each priority corresponds to specified color (different model has different colors).

Attention:

- Press  again on the drug list interface to save the priority setting.

3.8 Drug Library

1. Select menu "  " option → "Drug" to enter the interface.
2. The drugs in favorites are listed and displayed in line with its priority color.
3. Select  to find the end of drug list and then select ADD NEW FAVORITES to add new drugs into favorites among drugs library.
4. Select an intended drug in favorites, system will automatically return to the main interface; and drug name will be displayed on the information bar.
5. Select  to remove drug from drug favorites list. Select again to exit deleting status.
6. Select menu "  " option → "Drug library" → "drug" → directly select "  " to cancel selected drug, and then the drug name will no longer be displayed on the information bar.

Attention

- Only up to 50 kinds of drugs can be add into favorites. A prompt writing "Drug favorites has reached limit!" will be given if it is going to exceed limitation.

3.9 VTBI Setting

1. Select "VTBI" (Volume to be infused) option on the main interface to enter the VTBI setting interface.
2. After setting the VTBI, press the "START" button to run pump;
3. The VTBI display area will display the remaining VTBI and the remaining time alternately.

3.10 Zero Cumulative Infusion Volume

1. Select "Cumulative vol" on the main interface, and a prompt "Clear the cumulative infusion volume?" will be given on the interface.
2. Select "  " option to clear the cumulative infusion volume, or select "  " option to refuse clearing and return to the main interface.

4 Operation

4.1 Step-by-step Instructions

Press “ON/OFF” button for 3s to turn the pump on;

Install the syringe according to the method of 4.1.2;

Choose Syringe according to the current usage;

Refer to 4.1.4 to select the infusion mode;

Refer to 4.1.5 to set infusion parameters.

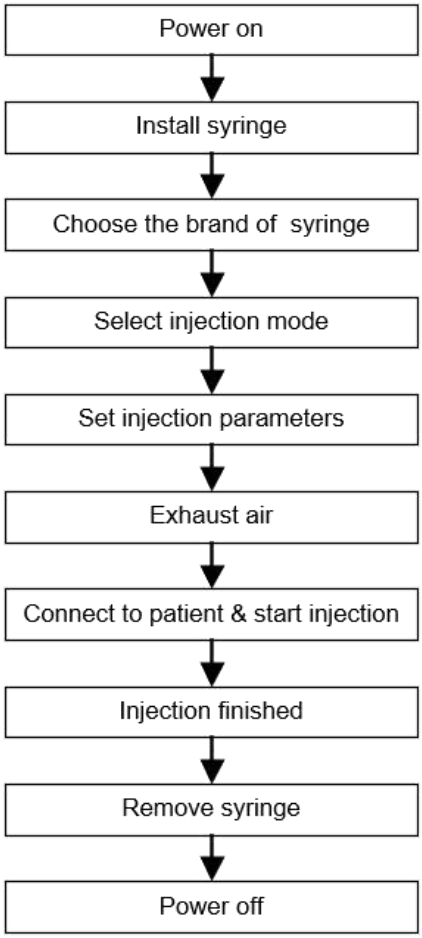
Exhaust air in tube before infusion;

Press the “START” button to start after connecting to patient;

Press the “STOP/BACK” button to finish infusion;

Disconnect from the patient, then open the door and remove the syringe;

Press and hold the “ON/OFF” button over 3S to power off.



4.1.1 Power On

After correct installation, please refer to the following steps to start the pump.

1. Press the “ON/OFF” button for 3 sec, the system will do self-testing first and the self-testing interface will be displayed on the screen.
   - First, the buzzer will sound a beep when the buzzer self-testing is completed;
   - Then the red and yellow alarm lights light up and then off, when the alarm indicator self-testing is completed;
   - Last, the loudspeaker emits a “Di-Di” sound, when the loudspeaker self-testing is completed;
2. The main interface like the figure 4-1 will appear after pump self-testing is completed.
   - At the same time, the prompt bar will remind the users whether to use the last treatment parameters or to use default parameters (this message will not appear after restore the system settings).
   - Follow the directions, press “START” button to use the last treatment parameter;
   - Follow the directions, press “STOP/BACK” button to use the default parameters;
3. The users can set new parameters according to the actual clinical requirements.

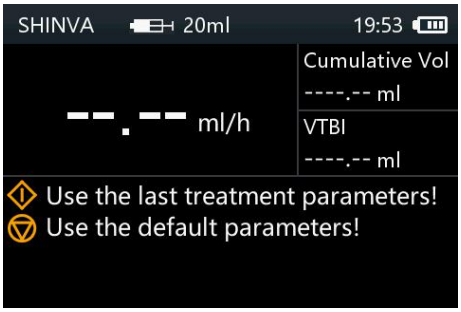


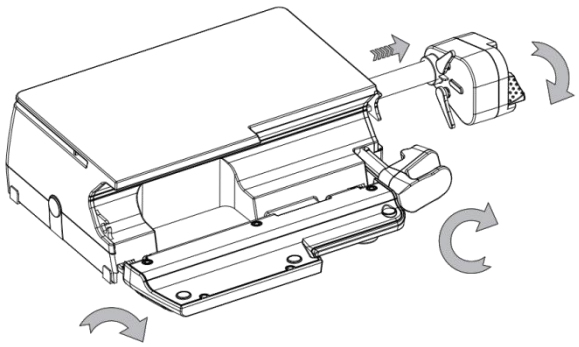
Figure 4- 1

⚠Caution:

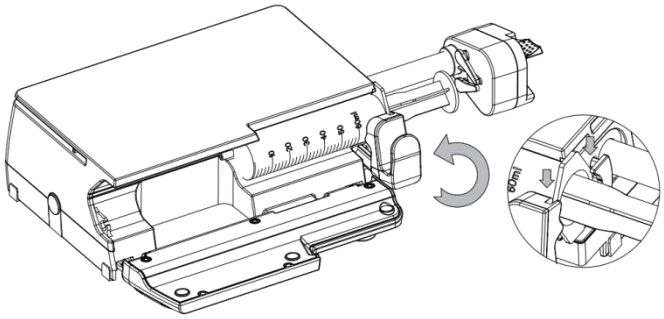
- Please carefully observe the self-test condition to make sure the loudspeaker, alarm light and buzzer are successful self-tested. Otherwise, do not use the pump.
- Only all faults are removed, it can be used normally and safely.

4.1.2 **Install Syringe**

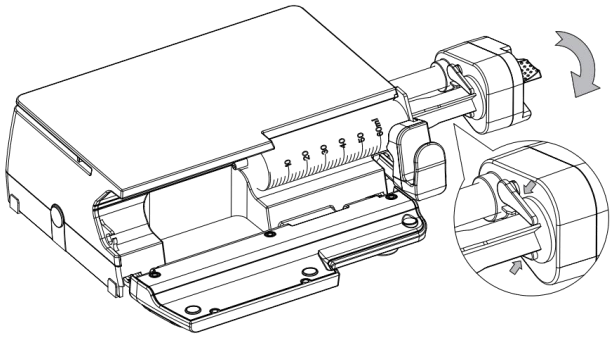
Install the syringe as following steps.



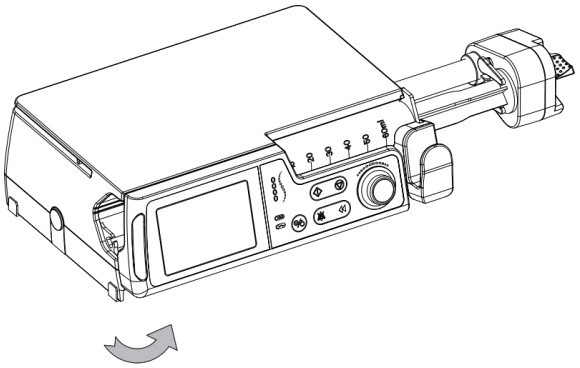
1. Open the door, squeeze the Plunger Release Lever and pull the pushing block outward gently to its largest scale. Pull out the Syringe Barrel Clamp and turn it 90 degrees to the right.



2. Press the flange of the syringe barrel into the flange clip. And then rotate barrel clamp back to fix the syringe barrel.



3. Clench the Plunger Release Lever on the Pushing block and push it toward to hold syringe plunger. Make sure both holders close around the syringe plunger.



4. Gently close the door to complete the syringe installation.

Attention:

- The flange of the syringe barrel should be firmly pressed into the inside of flange clip and must not be placed on the outside of the flange clip.

4.1.3 Select Syringe Brand

1. Please refer to the contents in 3.2 to select right syringe brand.
2. If the syringe intended to use is not recommended in the Chapter 17, correct calibration should be performed before using.
3. Always verify that the syringe selected is what is actually in use.

4.1.4 Select Infusion Mode

1. Select menu “ ” option → ”Mode”, choose the work mode according to actual needs.
2. Details about infusion modes, please refer to Chapter 5.

4.1.5 Set Infusion Parameter

1. After selecting the infusion mode, parameter setting interface of the intended infusion mode will appears automatically. Set the relevant parameters by moving the cursor to corresponding parameter option and then pressing the Rotary Knob or touching the screen.
2. Different infusion modes have different specific parameters. For details, please refer to Chapter 5.

4.1.6 Exhaust Air

1. To avoid hazards caused by air infusion, always discharge all air in the administration set before connecting to patients.
2. Double-click the “BOLUS” button and hold on for seconds (it’s only valid on the main interface) until all the air bubbles have been removed from the syringe and extension tube. About the setting method of FF rate and VTBI, please refer to contents in 1.1.4 and 3.4.

Attention:

- FF volume is not counted in the cumulative volume.
- When FF, must disconnect the pump from patients to avoid safety hazards.
- The default FF running rate is the maximum rate of each syringe size can be set.

4.1.7 Start Infusion

Connect to the patient after air is completely discharged.

- Press “START” button, a prompt “Please confirm the syringe size--XXml” will be displayed on the main interface as well as the syringe brand, rate, VTBI, occlusion pressure level and other information.
- Always verify that all parameters shown are in consistency of actual needs.
- Then press "START" button again to start infusion.
- When the pump is running, the working indicator will light up in sequence from top to bottom, and the pattern “  ” is dynamically running on the main interface.

4.1.8 Pause infusion

Press the “STOP/BACK” button to pause the infusion if the drug or syringe need to be replaced during the infusion process.

- After the drug or syringe is replaced, exhausting air should be performed according to the requirements of 4.1.6.
- If no need to change infusion mode or running parameters, press the “START” button to continue infusion according to last parameters.
- If the infusion mode or the parameters need to be changed, refer to the contents of 4.1.3-4.1.5.

4.1.9 Infusion Finished

1. If there is preset VTBI (Volume to be infused), the VTBI finished alarm occurs when the VTBI is completed and the system automatically enters the KVO mode;
2. If there is no preset VTBI (Volume to be infused), the infusion finished alarm occurs when the infusion of drug liquid in the syringe is completed and the system pump automatically enters the KVO mode;
3. For the KVO rate and VTBI settings, please refer to the relevant contents of KVO in 1.1.4 and 3.5.

4.1.10 Power Off

Disconnect the pump from the patient, and press and hold the "ON/OFF" button for 3s to switch the pump off.

5 Infusion Mode

5.1 Simple Mode

1. Select menu “  ” option → “Mode” → “Simple mode” to enter the interface as shown in Figure 5- 1. And then set the infusion rate.

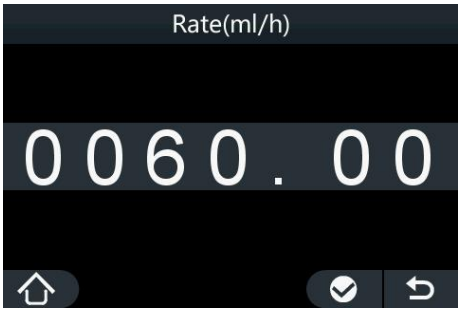


Figure 5-1

2. The settable parameters and ranges are shown as table below.

Mode	Parameters	Parameter range
Simple mode	RATE	2ml/3ml:0.01～60ml/h 5ml:0.01～150ml/h 10ml:0.01～300ml/h 20ml:0.01～600ml/h 30ml:0.01～900ml/h 50ml(60ml):0.01～2200ml/h
	VTBI	0.01～9999.99ml
	Remaining time	TIME=VTBI/RATE The time is automatically calculated after rate and VTBI are set.

5.2 Vol/T Mode

1. Select menu "☰" option → "Mode" → "Vol/T mode" to enter the interface as shown in Figure 5-2. Set VTBI and time, and the rate is automatically calculated.

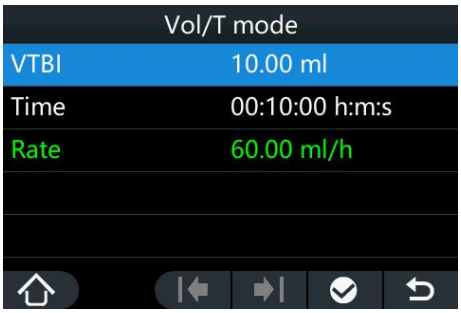


Figure 5-2

2. The settable parameters and ranges are shown as table below:

Mode	Parameter	Parameter range
Vol/T mode	TIME	00 : 00 : 01 – 99 : 59 : 59 (hh : mm : ss)
	VTBI	0.01～9999.99ml
	RATE	RATE = VTBI / TIME. The range is the same as the simple mode.

5.3 Vol/W Mode

1. Select menu "☰" option → "Mode" → "Vol/W mode" to enter the interface as shown in Figure 5-3. Users can set the drug name, weight, concentration, dose rate and other parameters according to actual needs.

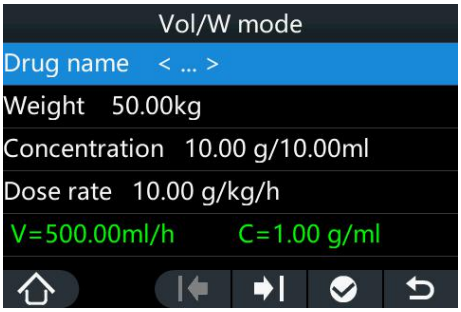


Figure 5-3

2. When setting the concentration parameter, it is necessary to set drug unit, drug amount and drug volume in sequence.
3. When setting the dose rate, it is necessary to set dose rate unit and dose rate in sequence.
4. The system automatically calculates the infusion rate and concentration according to the above parameters.
5. For the parameter ranges, please refer to the table below:

Mode	Parameter		Parameter range
Vol/W mode	Weight		0.01-300kg
	Concentration	Drug unit	g/mg/ug/ng/IU/mmol mIU/kIU/EU/mol/kcal/mEq/mcal/cal
		Drug amount	0.01-9999.99
		Drug volume	0.01-9999.99ml
	Dose rate units		Available in: x/min, x/kg/min, x/h, x/kg/h, x/24h, x/kg/24h，x/m2 /min、x/m2 /h、x/m2 /24h , and (x indicates units including ng、ug、mg、g、mIU、IU、kIU、EU、mmol、mol、mcal、cal、kcal、mEq)
	Dose rate		0.01-9999.99
	RATE		the same as the simple mode
	VTBI		the same as the simple mode
Drug concentration = amount / volume Infusion rate (with weight) = (dose rate * weight) / concentration Infusion rate (without weight) = dose rate /concentration			

5.4 Sequential Mode

1. Select menu “ ” option → “Mode” → “Sequential mode” to enter the interface as shown in Figure 5-4.

Figure 5-4

2. Set a series of different sequences (parameter groups) at one time, and the pump performs infusion function sequentially according to the preset sequence.
3. Up to 20 sequences can be set.
4. After setting the VTBI and time, the system automatically calculates the rate. The total VTBI and total time are the sum of the VTBI and time of each sequence.
5. Add a new sequence by selecting the last sequence and then touching it or pressing the Rotary Knob.
6. Select "⊠" option, the font color of sequences list will turn red. Click the sequence intended to be deleted to delete it. Click "⊠" option again to exit the "Delete" status.
7. Time and VTBI setting ranges are shown in the table below.

Mode	Parameter	Parameter range
Sequential mode	TIME	00 : 00 : 01 – 99 : 59 : 59 (hh : mm : ss)
	VTBI	The same as the simple mode
	RATE	RATE = VTBI / TIME. The range is the same as the simple mode

Attention:

- Never start infusion without setting VTBI and time.

5.5 Micro Mode

1. Micro mode is mainly used for low-speed and small-flow infusion in children or newborns.
2. Select menu "☰" option → "Mode" → "Micro mode" to enter the interface as shown in Figure 5-5.

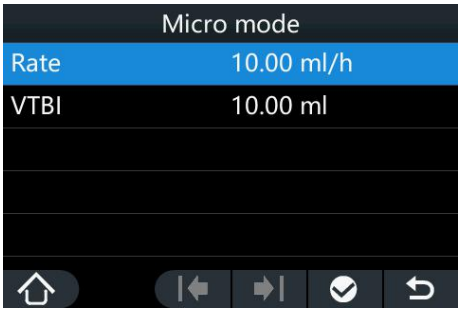


Figure 5-5

3. Rate and VTBI setting range are shown in the table below.

Mode	Parameter	Parameter range
Micro mode	RATE	0.01-100ml/h
	VTBI	0.01-1000ml
	Remaining time	TIME=VTBI/RATE The time is automatically calculated after rate and VTBI are set.

5.6 Intermittent Mode

1. Select menu "☰" option → "Mode" → "⏭" → "Intermittent mode" to enter the interface as shown in Figure 5-6.

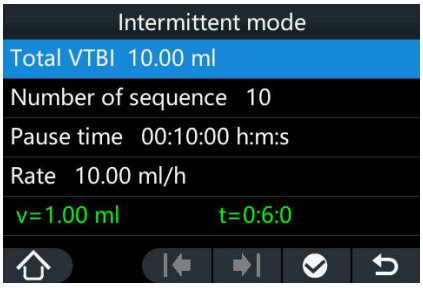


Figure 5-6

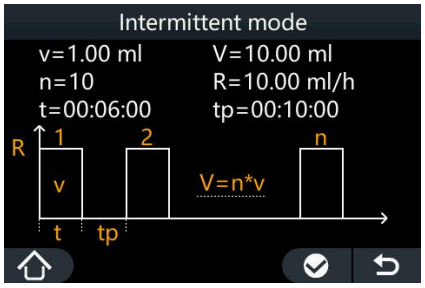


Figure 5-7

2. After entering the intermittent mode interface, user can set the total VTBI, number of sequences, pause time, rate. Then automatically jump to the interface as shown in Figure 5-7.
3. The range of parameters as shown in the table below.

Mode	Parameter	Parameter range
Intermittent mode	Total VTBI (V)	0.01-9999.99ml
	The number of sequences (n)	1-50
	Pause time (tp)	00 : 00 : 01 – 99 : 59 : 59 (hh:mm:ss)
	Rate (R)	the same as the simple mode
	Single sequence VTBI (v)	0.01-9999.99ml（v=V/n）
	Run time of single sequence (t)	00:00:01–99:59:59(hh:mm:ss) (t=v/R)

5.7 Ramp Up/Down Mode

1. By setting the ramp up time and ramp down time, the rate will automatically be increased within the preset ramp up time until the steady rate is reached. After a period of time, the rate is gradually decreased within the down time.
2. Select menu “ ” option → “Mode” → “ ”→ “Ramp up/down mode” to enter the interface as shown in Figure 5-8.

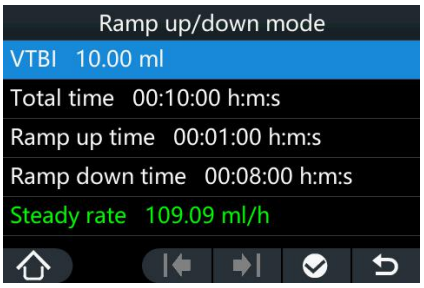


Figure 5-8

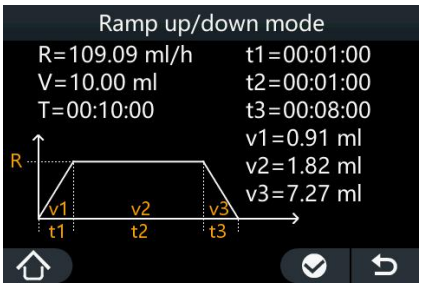


Figure 5-9

3. Set the VTBI, total time, ramp up time, ramp down time. Then automatically jump to the interface as shown in Figure 5-9.
4. The range of parameters is as shown in the table below.

Mode	Parameter	Parameter range
Ramp Up/Down mode	VTBI(V)	0.01-9999.99ml
	Total time(T)	00 : 00 : 01 – 99 : 59 : 59 (hh : mm : ss)
	Up time(t1)	optional fields
	Down time(t3)	optional fields
1. Steady rate, up rate, and down rate are automatically calculated, it cannot be input and modified, and the range is the same as simple mode;		

2. When ramp up time is null, total time > ramp down time: Steady time = total time – ramp down time, the rate of infusion will keep steady at the beginning and gradually fall at the end.
3. When total time = ramp down time, after starting pump, it goes directly to the down stage until infusion finished.
4. When ramp down time is null, total time >ramp up time: Steady time = total time – ramp up time, the rate will rise at the beginning and steady at the end.
5. When total time = ramp up time, the rise stage begins at the beginning and last until infusion is finished.
6. When ramp up time and down time are null, the steady stage will last until infusion finished.

5.8 TIVA Mode

1. Select menu "  " option → "Mode" → "  "→ "TIVA mode" to enter the interface as shown in Figure 5-10.

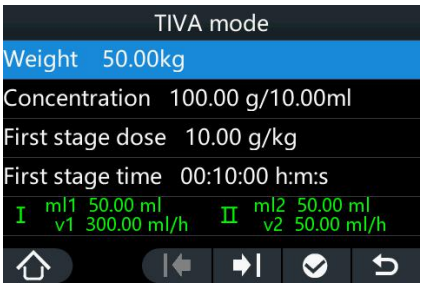


Figure 5- 10

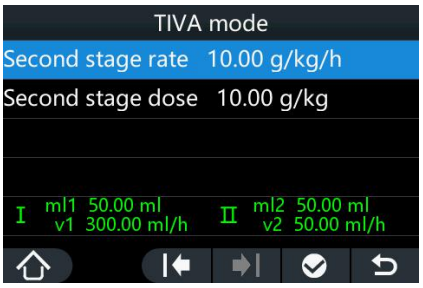


Figure 5- 11

2. Set the parameter such as weight, concentration, first stage dose, first stage time, second stage rate, second stage dose, etc.
3. Set the parameters according to "Vol/W" mode. The rate and VTBI of the first stage and the second stage are calculated automatically. The VTBI displayed on the main interface is the sum of first and second stages.
4. The range of parameters is shown as the table below.

Mode	Parameter	Parameter range
TIVA mode	First stage parameter	The same as the Vol/W mode
	First stage time	00 : 00 : 01 – 99 : 59 : 59 (hh : mm : ss)
	Second stage parameter	The same as the Vol/W mode

5.9 First Dose Mode

1. Select menu "  " option → "Mode"→ "  " → "First dose mode" to enter the interface as shown in figure 5-12;

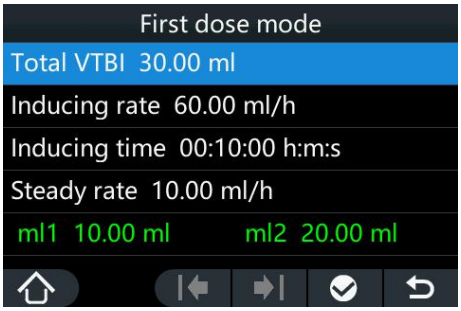


Figure 5-12

2. On the setting interface, Total VTBI, inducing rate, inducing time, Steady rate, etc

parameters can be set;

3. The settable parameters and ranges are provided in below table.

Mode	Parameter	Parameter range
First dose mode	Total VTBI	0.01-9999.99ml
	Inducing time	00 : 00 : 01 – 99 : 59 : 59 (hh : mm : ss)
	Inducting rate	The same as the simple mode
	Steady rate	The same as the simple mode
After adjustment, the pump runs in line with preset inducing time and rate until certain volume (V) is completed. and then machine will keep running at steady rate until the remaining volume (Total volume - V) is fully completed.		

Attention:

- Under any infusion mode, when the infusion rate exceeds the maximum permissible range, the font color of infusion rate display area will turn red or a prompt “parameter overrun” will be given in order to remind users of setting parameters correctly.

6 Alarm & Alarm Remove

The audible and visual alarms will be generated when there is alarm occurring. Please deal with alarms immediately. Alarms settings of last time are automatically saved when the alarm system is powered off.

Operator position description: Expected to be 1m away from the pump display screen.

6.1 Alarm List

Alarm Type	Priority	Reasons	Remedy Measures
Infusion finished	H	The drug liquid in syringe is infused completely.	Press the “STOP/BACK” button to terminate the alarm.
VTBI finished	H	The volume to be infused is completed.	Press the “STOP/BACK” button to terminate the alarm.
KVO completed	H	Under KVO mode, the preset KVO VTBI is completely infused.	Press the “STOP/BACK” button to terminate the alarm
Infusion is blocked	H	The extension tubing is knotted or blocked.	Press the “STOP/BACK” button to terminate the alarm. Press the “START” button to continue after check the knotted or blocked tubing.
		High drug concentration, but with a low occlusion pressure level setting.	Press the “STOP/BACK” button to terminate the alarm. Press the “START” button to continue after resetting a higher occlusion pressure level.

Alarm Type	Priority	Reasons	Remedy Measures
Syringe is improperly installed	H	1.The syringe is not properly installed in place. 2.Attempt to start an infusion without a syringe in place	Press the “STOP/BACK” button to terminate the alarm and reinstall the syringe properly.
Syringe falls off	H	1.Attempt to start infusion without the barrel clamp in place. 2.The barrel clamp does not clamp the syringe properly, causing the syringe to fall off.	Press the “STOP/BACK” button to terminate the alarm and ensure barrel clamp is in right place.
Abnormal running state	H	1.motor reversely runs 2.The actual running speed is higher or lower than the set speed	Unable to eliminate the alarm, remove the device from service immediately and contact the manufacturer.
Equipment failure	H	Storage error, pressure sensor abnormality, voltage abnormality, communication abnormality, etc.	Unable to eliminate the alarm, remove the device from service immediately and contact the manufacturer.
Power failure	H	AC power and internal battery fail at the same time	Unable to eliminate the alarm, remove the device from service immediately and contact the manufacturer.
Battery empty	H	internal battery runs out.	Connect to AC power, the alert cancels automatically.
Extension tubing off【Optional function】	H	1, extension tubing disconnects from syringe; 2, this alarm is exclusive to syringe size of 20ml, 30ml, and 50ml.	Press the “stop/back” button to terminate the alarm; Restart infusion after properly install the extension tubing and syringe.
Near infusion end	L	The time required for the infusion of the remaining liquid volume in the syringe is same as preset soon finish alarming time.	Press the “stop/back” button to terminate the alarm; Or keep working until infusion finished.
Near VTBI end	L	The time required for the infusion of the remaining VTBI amount is same as preset near VTBI end time	Press the “stop/back” button to terminate the alarm; Or keep working until infusion finished.
Low battery	L	The battery is to run out.	Connect to AC power, the alert cancels automatically.
Standby task completed	L	Time to complete standby is reached.	Press the “ON/OFF” button to enter the standby mode again, press the “STOP/BACK” button to terminate alarm.

Alarm Type	Priority	Reasons	Remedy Measures
Forgotten operation	L	While the machine is turned on, there is no any operation during the preset forgotten alarming time.	Terminate the alarm by pressing any button, except for SILENCE.
Pre-occlusion alarm 【Optional】	L	The actual pressure is reaching to preset occlusion alarm threshold.	Press the “STOP/BACK” button to terminate alarm. Restart infusion after solve the tubing knot or blockages.
Battery disconnected	L	the system does not detect connection of battery and or battery is abnormal.	Press the “STOP/BACK” button to terminate alarm. Connect the battery cables properly.
Note: The above alarms are technical alarms. the Pre-occlusion alarm is only valid while pressure is higher than 40kPa.			

6.2 Occlusion Triggering Time

When the syringe pump is running at medium speed (5ml/h) and low speed (1ml/h), the triggering time of occlusion alarm for the 10, 70, 130kPa is shown as table below. After the occlusion alarm is removed, the appropriate occlusion pressure level can be selected according to actual usage. The maximum allowed infusion pressure is 140 kPa.

Rate (ml/h)	Occlusion（kPa）	Triggering Time
5	10	50s
5	70	6min15s
5	130	11min56s
1	10	3min45s
1	70	34min43s
1	130	74min13s
0.01	10	6h45min
0.01	70	41h36min
0.01	130	78h17min

Attention:

- The triggering time is the main index of occlusion response characteristics. The above data and conclusion are obtained from the experiment of using 20ml SHIVA syringe and YUSHENG extension tube (specification: length:1.5m, total volume: 2.5ml, PVC materials). Please kindly note: the triggering time will be affected by syringe manufacturing technique, syringe specification and size, infusion rate, length of the extension tube, pressure, etc.
- Under the same occlusion and rate condition, the larger the actual pressure value is, the longer the alarm delay time is.
- Sunfusion pump is equipped with pressure release function to automatically release the pressure of pipeline system while the occlusion alarm occurs. Therefore, the

BOLUS caused by blockage can be ignored.

- Complying with EN/IEC 60601-2-24, test by using infusion analyzer (FLUKE IDA5) and running the pump at speed of 1ml / h (when low pressure alarm(10kPa) is set, the amount of BOLUS is: 0.05ml; when high-pressure alarm（130kPa） is set, the amount of the BOLUS is 1 ml.)

6.3 Voice Prompts

1. **Infusion begins:** A prompt “infusion begins” will be given when press “START” button to start infusion.
2. **Parameter overrun:** If the parameter values are exceeding permissible ranges, an alarm signal “Parameter overrun” will be given on the interface.
3. **AC power has been pulled out:** A prompt “AC power has been pulled out” will be given when turning pump on without connecting to AC power or disconnecting the AC power during infusion.
4. **Speed overrun:** a prompt “Speed overrun [0.01~xxml/h]” is given if user start infusion without setting rate or rate exceed permissible ranges.
5. **Press the 'on/off' for 1 sec to unlock:** After screen is locked automatically, a prompt "press" on / off ' for 1 sec to unlock" will be given to lead user to unlock the screen if there is any attempt to operate the pump.
6. **Uncalibrated accuracy:** If the user is intended to use syringe that not be calibrated, the machine will not able to start after press “START” button and will generates a prompt of “No calibration data”.

Attention

- While the Max-Limit function is enabled, permissible range of parameter or speed overrun is in consistent with Max-limit setting.

7 Alarm System

7.1 Alarm Priority

1. When multiple alarms conditions occur at the same time, the signal of the light alarm and audible alarm is consistent with the highest alarm level.
2. When multiple alarms conditions occur at the same time, the highest priority alarm is displayed prior to the secondary alarms. In other words, the inferior alarm can be displayed only until higher priority alarms are all released.
3. When the same priority alarms are activated at the same time, the device will process according to the default alarm program.

7.2 Alarm Expression

Alarm Priority	Sound expression	Light expression	LCD display
Low priority	“Di-Di” Loop alarm	Alarming indicator lights up in yellow.	Display the alarm reason with white text on a yellow background

	“Di-Di-Di” Loop alarm	Alarming indicator lights up in yellow.	Display the alarm reason(Low battery, forgotten operation, near VTBI end, near infusion end) with white text on a yellow background
High priority	“Di-Di-Di—Di-Di—Di-Di-Di—Di-Di” Loop alarm	Alarming indicator lights on in flashing red light at interval per 500ms.	Display the alarm reason with white text on a red background
Prompt signals	Voice broadcasting or texts notifications.	N/A	Display the notification with white text on a yellow background.

7.3 Characteristics of Audible Alarm Signals

1. The audible alarm signal sound pressure ranges from 45db to 80db at 1m distance.
2. The high priority alarm signal sound pressure level >= the low priority alarm signal sound pressure level.

7.4 Alarm Signal Inactivation Status

1. The audible and visual alarming signals disappear only when the alarms are resolved or terminated.
2. Press "SILENCE" button while a high priority alarm occurs, “ ” will be displayed on the LCD, the alarm sound will be paused and the red alarm light will still flash at the original frequency; after 1min, the device will restore previous alarm status.
3. Press "SILENCE" button while a low priority alarm occurs, “ ” will be displayed on the LCD, the alarm sound will be paused, the yellow alarm light will still bright, and the buzzer will sound beep at the interval of 2s; after 1min, the device will restore previous alarm status.
4. Press the “STOP/BACK” button to terminate alarm signal inactivation states (prompt signal is terminated at the same time)
5. Alarm signal characteristics: duration: 70ms, level: 50dB, frequency: 2.5kHz.

Attention:

- When the equipment failure, power failure, and battery empty alarm occur, it’s invalid to press the “SILENCE” button.
- The silence state disappears when another alarm is generated.

8 Auxiliary Functions

8.1 Standby

1. Under the Non-operating condition, press the “ON/OFF” button to enter the standby mode, and the interface will display as the standby mode.
2. The default standby time is 1min. The user can modify the standby time at any time

when the standby mode is in progress.

3. After the standby time setting is completed, the system returns to the main interface, an audible prompt “System standby completed” and a visual prompt “System standby completed” will be given, and the yellow alarm light is on. Press the “ON/OFF” button to enter the standby mode again.
4. Under standby mode, the forgotten operation will not be triggered.

8.2 Change Rate During Running

During the process of Simple Mode, Vol/T Mode, Micro Mode, and Vol/W Mode, touch this rate display area or move the cursor to the rate display area and then press the Rotary Knob to enter the rate changing interface. After adjusting the rate or dose rate, the pump will run at the modified speed. The rate will restore to the previous rate after the pump stops infusion.

8.3 Syringe Calibration

1. When use a syringe brand not recommended or when the infusion accuracy error is serious, calibration need to be performed.
2. Pull syringe plunger outside barrel more than its largest scale and then install it on pump properly. (For example: the largest scale of 50/60ml syringe is 50ml, but pull it to 52ml scale.)
3. Double click and hold BOLUS button to push the syringe to its largest scale(50ml).
4. Select menu “  ” option → “System setting” → “  ”→ “System maintenance” → “Enter password” → “Accuracy calibration” to enter the calibration interface.
5. Follow the instructions to confirm syringe size: if it is right, then press START button to move to next step; otherwise, press STOP/BACK button to return.
6. A prompt to remind user of manually eliminating mechanical gaps and pulling the syringe to largest scale. If the step2-step3 mentioned above are finished, you can confirm by directly pressing START button to move forward; otherwise, follow the instructions to finish Step2-Step3.
7. After confirmation, the calibration is started.
8. When the calibration is completed, the system will automatically stop running and display “Calibration success！” on the interface.
9. Do not operate pump during calibration. Press the “STOP/BACK” button to exit the calibration, but the calibration data will not be saved.

Attention:

- Please carefully follow the instructions on interface to perform calibration.

8.4 Anti-Bolus

1. Select menu “  ” option → “System setting” → “  ”→ “System maintenance” → “Enter password” → “Anti-bolus” to enter the interface.
2. The anti-bolus function is enabled by default.
3. After entering the anti-bolus interface, a prompt “Close the Anti-bolus function?” will be

given on interface with red font color. Press “” option to disenable the anti-bolus function; Press “” option to return to the previous interface and the current operation is not saved.

4. Enter the anti-bolus interface while the anti-bolus function is disenabled, it will display “Open the Anti-bolus function?” on the interface with white font color. Press “” option to enable the anti-bolus function; Press “” option to return to the previous interface and the current operation is not saved.
5. After triggering the occlusion pressure alarm, the motor reverses to release the pressure in the tube in order to prevent additional dose shock to the patient.

8.5 Restore Factory Settings

1. Select menu “” option → ”System setting” → “”→ ”System maintenance” → ”Enter the password”→”Recovery ” to enter the setting interface.
2. The system will prompt “Restore the system settings?”. Select “” option to complete the setting; select “” option to return to the previous interface and current parameters are not saved.

8.6 WLAN Function

1. Sunfusion pump are equipped with a WIFI module (optional) which enable the pump to communicate with the infusion central station software or the infusion management system.

   Through Internet:

   - The pump transmits infusion parameters, alarm information, prompt information, etc, to the infusion central station software or infusion management system in real time.
   - For further details, please refer to the manual of the infusion central station software or infusion management system.

2. When using the wireless module to connect the pump to the infusion central station software or the infusion management system.

   - The wireless icon “”in the upper right corner of the interface indicates the working status of the wireless module.
   - No icon means wireless module isn’t equipped.

3. Technical Index for WIFI

ITEMS	Description		
	IEEE 802.11b	IEEE 802.11g	IEEE 802.11n(HT20)
Operation Frequency (MHz)	2412—2472	2412—2472	2412—2472
Modulation	DSSS	OFDM	OFDM
EIRP (dBm)	<18	<18	<18

Attention:

- The setting of the wireless network must be carried out by a technician authorized or

designated by our company.

- Sunfusion Pump with inserted Wifi module may be interfered by other equipment complied with relevant requirements of CISPR.

9 Maintenance

To avoid device damages, the following rules are intended to be complied with.

Hereby acknowledge that the responsibilities of damages or accidents which are caused by violating following rules should not be taken by our company. This chapter is only for provision of proper materials and methods of maintenance and cleaning.

Please make sure no dust on the devices and any other accessories.

9.1 Regular Cleaning

- Before cleaning, must shut down the device and disconnect the AC power.
- Regularly conduct cleaning every 3 months; the cleaning frequency should be increased if the devices are used in a place with serious environmental pollution or large wind and sand or there is obvious dirt on the pump surface.
- Clean the devices with 95% alcohol solution and disposable wet wipes. Never use the corrosive chemical cleaners in that they can damage the plastic parts of devices;
- Use a dry soft cloth to clean the AC interface and other connectors, and make sure the socket and interface are dry before cleaning. Never use abrasive materials such as steel balls or silver polish to clean devices.
- It is forbidden to sterilize by means of using equipment such as autoclave. Do not use dryer or similar product to dry devices.
- If need to dismantle the pushing block, handle, etc. for cleaning, please contact a dealer.
- If liquid spills on the pump, please check if the device is working normally; if necessary, should conduct tests of insulation and leakage current.
- Must prevent liquid entering the device enclosure; dry treatment must be conducted before reusing the devices to ensure safe and normal work.

9.2 Routine Maintenance

9.2.1 Battery Maintenance

The rechargeable Li-battery is equipped to enable the devices can work normally in the case of transferring patients in hospital or sudden interruption of power. Once connected to AC power, the battery can be charged no matter the device is power on or off. If battery is charging while the device is on, the battery icon  on the right corner of the interface is working. When the icon is still with 4 levels, it indicates that the battery is fully charged. (Caution: Only charge the battery inside the device.)

The battery will be activated to supply power for the pump automatically if there is power failure or interruption of mains supply.

1. If it is the first time to use battery, a complete optimization cycle should be implemented as following steps:
    1) Under the condition that mains will not be interrupted, continuously charge the battery until it is fully charged;
    2) And then start the device at any running speed to exhaust the battery power;
    3) Charge the battery again until it is fully charged.
2. When the running duration of battery is obviously shorter than before, battery optimization should be conducted as well.

    Optimize the battery as following steps:
    1) Press the STOP/BACK button to stop infusion. When the pump stops working, disconnect the connection between patients and pump;
    2) Shut down the pump and connect it to AC power to charge the battery continuously until battery is fully charged;
    3) Disconnect the power and turn the pump on, then operate the pump at any running speed to discharge the battery until the pump shut down;
    4) Connect the pump to AC power again to charge the battery continuously until battery is fully charged.
3. If do not use the pump for a long time, please charge the battery every 3 months to avoid battery damages.
4. The essential performances of battery are to decline as time goes by. Therefore, please conduct inspection to battery essential performances once every 3 months (inspection procedures are the same as second optimization steps 1)-3)). Notices: The running speed is fixed at 5ml/h; record the actual running time and compare it with the time specified in manual; if the actual running time of battery and alarm time of battery low/empty (after being fully charged) are shorter than the specified time, please contact service personals to replace the battery.
5. If the battery cannot be charged or discharged normally, please conduct service personals for help.
6. If replacement of battery is needed, please contact service personals to replace; or follow the steps as below to replace it under the instructions of professional operators:
    1) Shut down the pump, and disconnect the power;
    2) Put the pump at a flat place;
    3) Open the battery door to unlock the battery compartment;
    4) Take out the old battery, and put the new battery in the compartment, then lock the compartment;

5) Close the battery door, then put the pump rightly;

6) When do not use the pump, please disconnect the power to avoid battery damages due to over-discharge.

⚠Caution:

- Do not expose battery to excessive temperature, which may cause explosion.
- Put the battery out of children's reach.
- Only use the battery specified by manufacture.
- The support time of battery is affected by using time, running speed, working environment and not fully charged.
- Improper storage and maintenance will shorten the longevity of battery.

9.2.2 Device Maintenance

When replacing the fuse, please make sure the specification of the replaced fuse is the same as the specification (T2A/250VAC) that specified in this manual.
If using fuse with different specification, it may burn out immediately, and even cause damages to device.

⚠Caution:

- Should not perform maintenance when the pump is running and is connected to the patients.

10 Recommended Inspection and Safe Operation

For ensuring the safe use of pump and extending its lifetime, the user can verify its effectiveness of functions and the safety of operations by conducting the procedures specified as below. Some items can be performed by operators, and some are intended to be performed by authorized distributers and manufacturer.
Inspection should be performed once every 6 months.

10.1 Appearance Inspection

- Appearance inspection: no cracks or damages
- Buttons inspection: The button can be pressed smoothly and effectively.
- Display screen inspection: Display normally and touch function is valid.

10.2 Power Cable Inspection

- Check the appearance of the power cable. If there is damage to its skin and the connection between plug and socket is improper, please contact an authorized distributer to repair.
- If the power indicator does not light and pump cannot be turned on while connecting to the AC mains power. Please contact an authorized distributer to repair.

10.3 Infusion Accuracy Inspection

- Use a graduated cylinder and a stopwatch to check infusion accuracy at least every 3 months. The inspection conditions are shown as table below:

Syringe	Rate	Infusion time	Liquid volume in graduated cylinder
SHINVA 50ml	60ml/h	10min	9.8-10.2ml/3ml/3ml

- When syringe SHINVA is unavailable, the syringes recommended in this manual can also be used for testing. When the test result exceeds the above cylinder volume range, please consult the service staffs or technicians for calibration.

10.4 Alarms Inspection

Inspection methods for several essential alarms are described as below. It is recommended that perform alarm system inspection at least once every 3 months to ensure that the alarm system can work normally.

- The alarm system self-test, refer to contents in 4.1.1
- Syringe is improperly installed: Alarm “syringe is improperly installed” occurs when starting the pump without correctly installing the syringe plunger to its holder, or occurs when the syringe plunger separate from the pushing block during infusion.
- Syringe falls off: Alarm “syringe falls off” occurs if there is any attempt to start infusion without properly setting the plunger holder, or the plunger release lever does not securely clamp the syringe during infusion.
- Infusion is blocked: Fill the 50ml syringe with water, and connect it to the pressure gauge, then start the pump at rate of 200ml/h. During infusion, carefully observe if the triggering alarm pressure of each occlusion pressure level alarm meets the requirements in the pressure alarm range in 1.1.4.
- Near infusion end: After installing a 50ml syringe correctly, set the soon finish time of 1 min and then start the pump at rate of 120 ml/h; the near infusion end alarm occurs when the 2ml marking line is reached.
- Infusion finished: After correctly installing a 50ml syringe, pull the syringe to its 20ml scale and start the pump at rate of 200ml/h. The infusion finished alarm should occur if there is no remaining volume (after 6min).
- VTBI finished: After correctly installing a 50ml syringe, start the pump at VTBI of 1ml and rate of 60ml/h. The VTBI finished alarm should occur when the VTBI on main interface is displayed as zero (after 1min).
- Electrical safety test: Please test the insulation voltage, leakage current and grounding resistance according to the methods of EN/IEC60601-1 and EN/IEC60601-2-24.

11 Transport and Storage

When transporting or storing, use original package as possible and adhere to ambient temperature, humidity and pressure described in 1.1.4.

12 Disposal

Considering the lifetime of components and safety performance of medical equipment, the service life of pump shall not exceed 7 years calculated from the production date. The expired products should be manipulated according to local laws. It is dangerous to use expired products.

13 Troubleshooting

Faults	Possible Causes	Possible Remedies
No display	Battery is exhausted	Connect to AC mains power
	System breaks down.	1.Reboot the pump; 2.Contact manufacturer
Low battery alarm after start up	1. Battery is not timely charged after use; 2. Pump is idle for too long	Connect to AC mains power
	1. Improperly use the battery 2. Out of battery life; 3. battery id damaged.	Replace battery
The pushing block can't be moved smoothly	There is drug liquid on the moving rod.	Wipe it with alcohol
infusion rate is inaccurate	Use an unmatched syringe.	Use the recommended syringe or correctly calibrate the syringe
	The syringe flange is not inserted in place.	Correctly reinstall the syringe
There is back blood when infusion begins	1. The syringe pump is not started after needle head is inserted into patient. 2. The mechanical gaps is not eliminated.	1. Start the syringe pump 2. Press "BOLUS" key to push the blood into the vein
No response when touching screen	1. Touch screen is not calibrated; 2. Screen is damaged.	1. Conduct screen calibration; 2. replace a new screen.
False triggering of occlusion alarm	1. Occlusion pressure level is too low; 2. Pressure is not precise.	1. Adjust a higher pressure level; 2. Conduct pressure calibration.
False triggering of installation error	The syringe plunger is not fixed in place.	Reinstall the syringe to make its plunger fixed in place.

14 Infusion Features

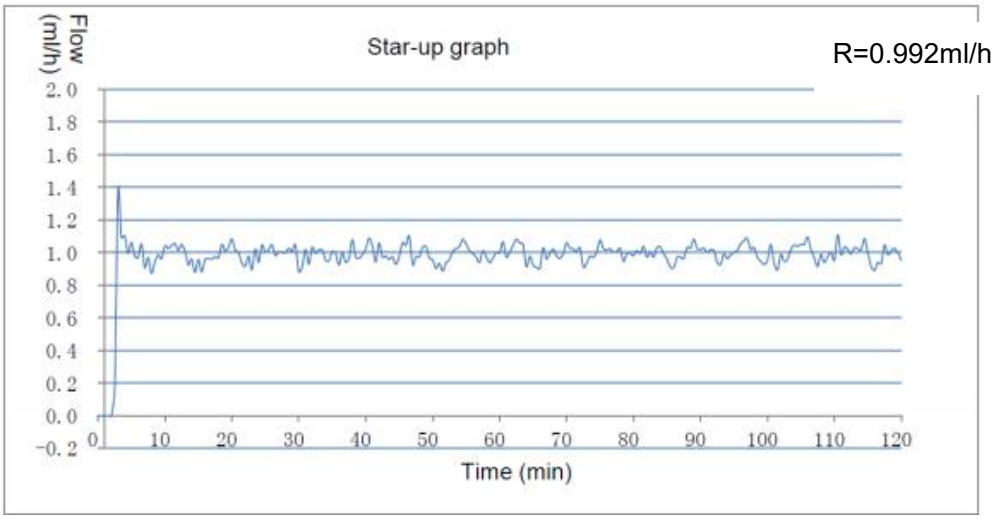
14.1 Infusion Accuracy

Sunfusion pump infusion accuracy is within ±2% after calibration. If user or supervisor intends to test pump according to EN/IEC60601-2-24, the syringe shall meet the following requirements: the tolerance of syringe cross section dimension should be within ±1%; the each joint part shall not have tiny leakage under the ±13.33kPa system pressure (Liquid leaks under positive pressure, Air enters into the infusion system under

negative pressure). Perform test after correct calibration.
Number of sample：3PCS.

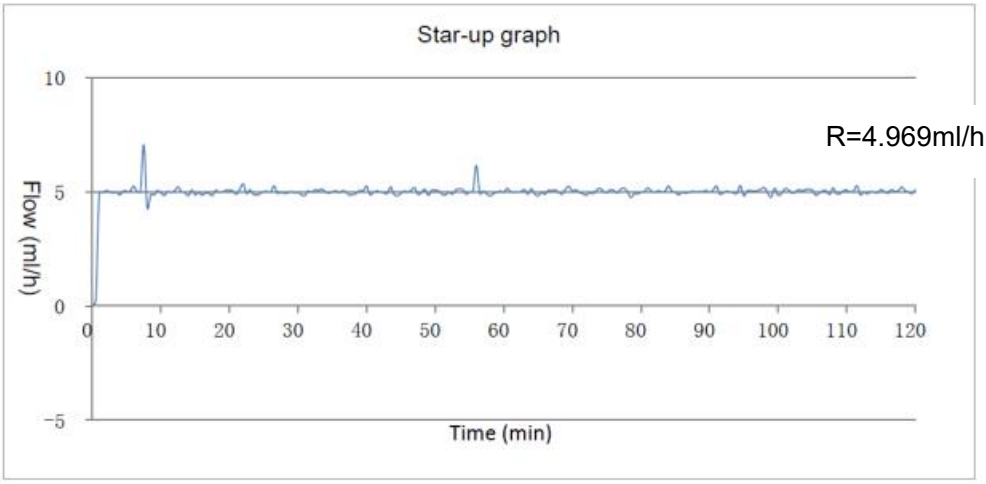
14.2 Infusion Accuracy Features

Typical infusion accuracy curve is provided as below, showing the essential performances while starting infusion and the infusion changes that occur within a certain time after reaching the normal infusion rate.
Pictures for reference only, goods in kind prevail.
According to the data collected during the two-hour measurement cycle.
Sampling rate: 1ml/h
Interval time: △t=0.5min
Test period: T=120min
Rate: 1ml/h



Pic.1 Up curve made from the collected data of 2hrs (1ml/h)

Sampling rate: 5ml/h
Interval time: △t=0.5min
Test period: T=120min
Rate: 5ml/h



Pic.2 Up curve made from the collected data of 2hrs (5ml/h)

Attention:

- Testing Conditions: Test equipment: Sunfusion Anim-5; Syringe brand: SHINVA;
- Syringe size: 50ml (60ml).
- The infusion accuracy of the syringe pump does not reflect clinical criteria such as the patient's age, weight, medication.
- The test may be affected by the environment (such as pressure, temperature, humidity, infusion components, etc.)

14.3 Trumpet Curve of infusion Accuracy

Trumpet curves explains the variation range of average maximum and minimum rate in the observation window. The following results are the testing data according to EN/IEC60601-2-24. Please check relevant National Standard for more information if needed.

Sampling rate: 1ml/h

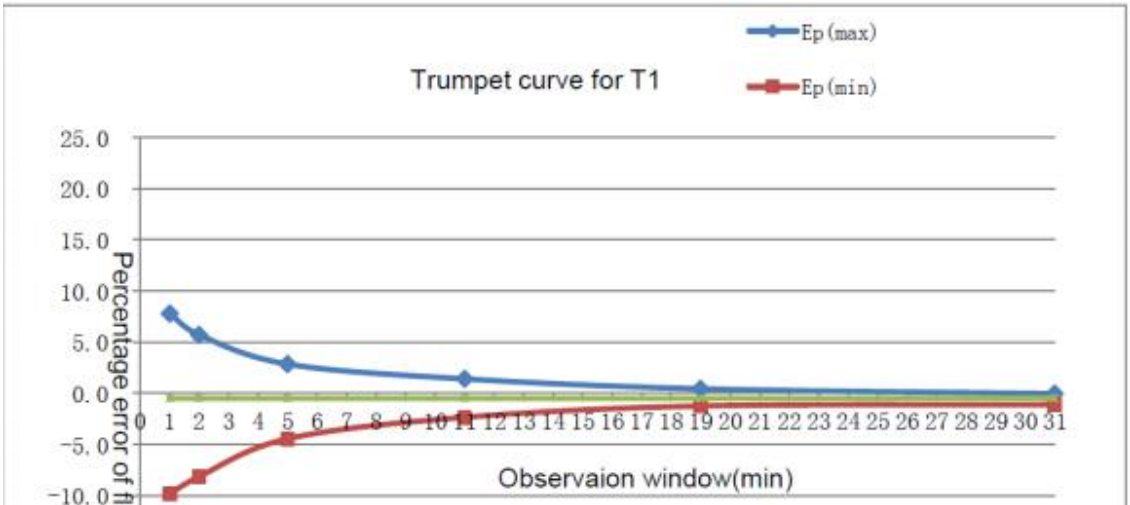
Interval time: △t=0.5min

Observation window: p△t=2、5、11、19、31min

Maximum measurement error of the observation window during the specified duration: Epmax(%)

Maximum measurement error of the observation window during the specified duration: Epmin(%)

Average error: A (%)



Time(min)	2	5	11	19	31
Max Accuracy error(%)	5.721	2.852	1.412	0.445	-0.034
Min Accuracy error(%)	-8.106	-4.433	-2.343	-1.235	-1.108

Trumpet curve

Pic.3 Trumpet curve made from the collected data of the 2nd hour (1ml/h)

Sampling rate: 5ml/h

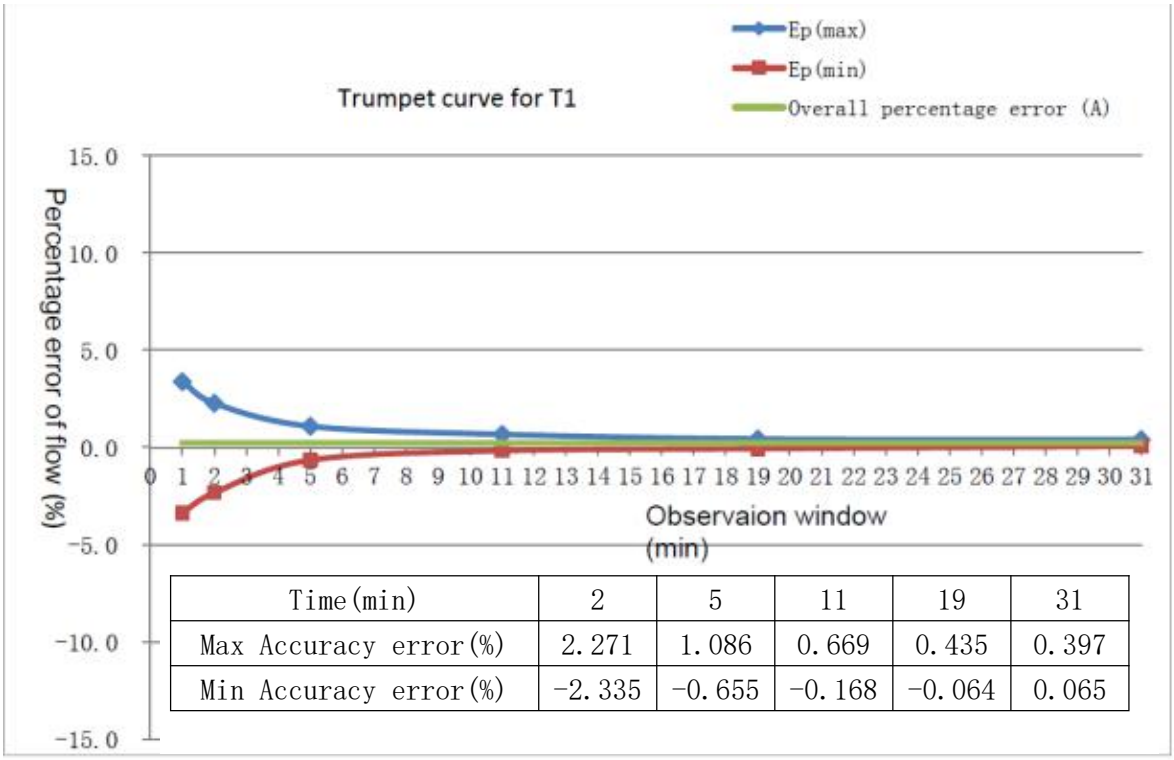
Interval time: △t=0.5min

Observation window: p△t=2、5、11、19、31min

Maximum measurement error of the observation window during the specified duration: Epmax(%)

Maximum measurement error of the observation window during the specified duration: Epmin(%)

Average error: A (%)



Time(min)	2	5	11	19	31
Max Accuracy error(%)	2.271	1.086	0.669	0.435	0.397
Min Accuracy error(%)	-2.335	-0.655	-0.168	-0.064	0.065

Trumpet curve

Pic.4 Trumpet curve made from the collected data of the 2nd hour (5ml/h)

Attention:

- Testing Conditions: Test equipment: Sunfusion Anim-5; Syringe brand: SHINVA;
- Syringe size: 50ml (60ml)
- The above data are typical values under this test conditions. The actual data varies in different test conditions. Please refer to the data tested by the product you purchased.

15 Accessories

Item	Lithium battery	Pole clamp	Power cord

⚠Caution:

- Only use the accessories specified in this chapter. Other accessories that do not meet standard requirements may damage the pump.
- If damage on accessory package or accessory is found, do not use the pump.

16 Packing List

Item	Quantity (pc)	Item	Quantity (pc)
Syringe pump	1	Pole clamp	1
Power Cable	1	Operator's Manual	1

17 Recommended Syringe Brand

No.	Brand	No.	Brand	No.	Brand
－01－	BBRAUN	－03－	SHINVA	－05－	Class B
－02－	BD	－04－	Class A	－06－	Class C

⚠Caution:

- Calibration is required when using a new syringe brand for the first time.

Attention:

- Always verify that the syringe brand selected is what is actually in use.

18 EMC

The Sunfusion syringe pump comply with the EMC standard EN/IEC 60601-1-2

Note

- Using accessories, cables or sensors not included in standards, may increase the syringe pump's electromagnetic emission, or decreased the syringe pump's electromagnetic immunity.
- Never use the syringe pump close to or stacked with other equipment. When necessary, should observe the syringe pump closely, ensure the syringe pump could running properly under used configuration.
- Need special protection of syringe pump's EMC, also the installation and maintenance should under the environment that meets the following EMC information.
- Avoid using the syringe pump with MIR or similar devices, otherwise the syringe pump may failure and equipment breakdown because of electromagnetic interference.
- This syringe pump is intended to be used by healthcare professionals only. Device/system may be disturbed by radio or disturb the operation of nearby equipment, mitigation measures may be necessary, such as reorienting, relocating the equipment or shielding corresponding sites.
- Portable or mobile RF communication devices may affect the performance of syringe pump.
- User should install and use the machine by following the EMC information in random file.
- Class A equipment is intended for use in hospital environment, due to conducted and radiated disturbances, in other environments may come with potential difficulty to ensure EMC.

- Using accessories, transducers or cables outside of regulation with equipment and system, may cause the equipment or system increase the electromagnetic emission, or decrease the electromagnetic immunity.

Cable information

Item	Cable length（m）	Whether Shield
Power Cable	1.8	NO

Guidance and manufacturer’s declaration – electromagnetic emission		
The models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 are intended for use in the electromagnetic environment specified below. The customer or the user of the models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 should assure that they are used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 uses RF energy only for its internal function. Therefore, theirs RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	The models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 are suitable for used in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is needed: **Warning**: The models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 are intended for use by healthcare professionals only. The models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM] or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and declaration – electromagnetic immunity

The models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 are intended for use in the electromagnetic environment specified below. The customer or the user of the models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 should assure that they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 0,5 cycle 70 % UT (30 % dip in UT) for 25/30 cycles < 5 % UT (>95 % dip in UT) for 5 sec <5% UT (>95 % dip in UT) for 5/6 sec	< 5 % UT (>95 % dip in UT) for 0,5 cycle 70 % UT (30 % dip in UT) for 25/30 cycles < 5 % UT (>95 % dip in UT) for 5 sec <5% UT (>95 % dip in UT) for 5/6 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Sunfusion Syringe pump Equipment requires continued operation during power mains interruptions, it is recommended that the Sunfusion Syringe pump be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m,30 A/m	3 A/m,30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE	UT is the a. c. mains voltage prior to application of the test level.		

Guidance and declaration – electromagnetic immunity

The models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 are intended for use in the electromagnetic environment specified below. The customer or the user of the model Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 should assure that they are used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz Outside ISM banda 6 Vrms in ISM and amateur radio bands	3 V (V1) 6V (V2)	Portable and mobile RF communications equipment should be used no closer to any part of the Sunfusion Syringe pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$ d = $[3.5/E1]\sqrt{P}$ 80 MHz～800 MHz d = $[7/E1]\sqrt{P}$ 800 MHz～2.7 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m (E1)	where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF

transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 are used exceeds the applicable RF compliance level above, the models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3

The models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models Sunfusion Anim-5, Sunfusion Semi-1, Sunfusion Erch-3 are recommended below, according to the maximum output power of the communications equipment.

Separation distance according to frequency of transmitter (m)

Rated maximum output power of transmitter W	150 kHz to 80 MHz outside ISM bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $[3.5/\mathrm{E1}]\sqrt{P}$	800 MHz to 2.7 GHz $[7/\mathrm{E1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

19 Manufacturer

Hunan Beyond Medical Technology Co., Ltd.
Add: Beyond Zone, Lijiacun Rd, Xueshi Street, Yuelu District, 410208 Changsha, China.
Tel: +86-731-82564299
en.csbeyond.com

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WellKang Ltd (www.CE-marking.eu)
Enterprise Hub, NW Business Complex,
1 Beraghmore Road,Derry, BT48 8SE,
Northern Ireland,UK

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